The Community

American Health Information Community

June 3, 2008
8:30 a.m. - 1:45 p.m.

Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 800
Washington, DC 20201

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8:30 a.m. - 1:45 p.m. (EDT)

Hubert H. Humphrey Building, Room 800
200 Independence Avenue, S.W.
Washington, DC 20201

8:30 a.m. **CALL TO ORDER –** *Secretary Leavitt*

8:35 a.m. **Introductory Comments** – *Secretary Leavitt*

8:40 a.m. **Comments** – *Kerry Weems, Vice-Chair; Acting Administrator, Centers for Medicare & Medicaid Services*

8:45 a.m. **Comments Focusing on the Health IT Strategic Plan** – *Robert M. Kolodner, National Coordinator for Health IT*

9:00 a.m. **AHIC Standing Committee of the Whole: Successor**

– *Mark McClellan, The Brookings Institution*

9:30 a.m. **Status Report on Accelerating Interoperability**

– *John Loonsk, Office of the National Coordinator for Health IT*

10:00 a.m. **Healthcare Information Technology Standards Panel Update**

– *John Halamka, Healthcare Information Technology Standards Panel*

10:30 a.m. **Certification Commission for Healthcare Information Technology Update**

– *Mark Leavitt, Certification Commission for Healthcare Information Technology*

11:00 a.m. **AHIC Interoperability Priorities Discussion (continued from April AHIC Meeting)**

– *John Loonsk, Office of the National Coordinator for Health IT*

11:45 a.m. **BREAK**

12:00 p.m. **Workgroup Recommendations**
Personalized Healthcare Workgroup (Pharmacogenomics)

– *Doug Henley, American Academy of Family Physicians*
– *Janet Warrington*

12:30 p.m. **Update from State Alliance for e-Health / National Governors Association**

– *Jodi Daniel, Office of the National Coordinator for Health IT*
– *Kathleen Nolan, State Alliance for e-Health*

1:00 p.m. **Defining Key Health Information Technology Terms**

- *Karen Bell, Office of the National Coordinator for Health IT*
- *Jane Horowitz, The National Alliance for Health IT*
- *Don Mon, American Health Information Management Association*
- *Bill Bernstein, Manatt, Phelps & Phillips LLP*

1:30 p.m. **Public Comment**

1:45 p.m. **ADJOURN**

Meeting Report

American Health Information Community
April 22, 2008

The American Health Information Community (AHIC), a federally chartered commission formed to help advance President Bush's call for most Americans to have electronic health records (EHRs) within 10 years, held its 21st meeting on April 22, 2008, at the Hubert H. Humphrey Building, Room 800, 200 Independence Avenue SW, Washington, DC, 20201.

The purpose of the meeting was to bring together Community members to continue discussion of steps toward ways to achieve its mission of providing input and recommendations to the Department of Health and Human Services (HHS) on how to make health records digital and interoperable, and ensure that the privacy and security of those records are protected in a smooth, market-led way. The meeting focused on: (1) a discussion of AHIC priorities and use case options for 2009, (2) an AHIC 2.0 successor update, and (3) presentations from the Quality Workgroup, Clinical Decision Support *Ad Hoc* Planning Group, Consumer Empowerment Workgroup, and Confidentiality, Privacy and Security Workgroup. The meeting also included an update on the initiatives of the Office of the National Coordinator (ONC), and an update on state-level health information exchanges (HIEs).

HHS Secretary Michael O. Leavitt chairs the Community. The remaining 16 members, selected by Secretary Leavitt, are key leaders in the public and private sectors who represent stakeholder interests in advancing the mission of the Community and who have strong peer support. Members serve two-year terms.

A summary of the discussion and events of that meeting follow.

Call to Order

Joining Secretary Leavitt around the table were:

Robert Kolodner, MD, National Coordinator for Health Information Technology

Craig Barrett, PhD, Chairman of the Board, Intel

Alissa Fox, Vice President for Legal and Regulatory Affairs, Blue Cross Blue Shield Association (Ms. Fox represented Scott Serota, President and CEO of the Blue Cross Blue Shield Association

Lillee Gelinas, RN, MSN, FAAN, Vice President and Chief Nursing Officer of VHA, Inc.

Julie Gerberding, MD, Director of the Centers for Disease Control and Prevention (also represented by Leslie Lenert, Director of the National Center for Public Health Informatics, Centers for Disease Control and Prevention)

Gail Graham, Director of Health Data at the Department of Veterans Affairs, Veterans Health Administration

Dan Green, Deputy Associate Director, Office of Personnel Management (Mr. Green represented Linda Springer, Director of the Office of Personnel Management)

Douglas Henley, MD, Executive Vice President, American Academy of Family Physicians

Kevin Hutchinson, At-Large AHIC member; CEO of Prematics, Inc.

Howard Isenstein, Vice President of Public Affairs and Quality, Federation of American Hospitals (Mr. Isenstein represented Charles N. (Chip) Kahn III, President of the American Federation of Hospitals)

Stephen Jones, Ph.D, Principal Deputy for the Assistant Secretary of Defense for Health Affairs, Department of Defense (Mr. Jones represented S. Ward Casscells, Assistant Secretary for Health Affairs, Department of Defense)

Bettijoyce Lide, Scientific Advisor for Health Information Technology, National Institute of Standards and Technology's Information Technology Laboratory (Ms. Lide represented Cita Furlani, Director of the NIST Information Technology Laboratory)

E. Mitchell (Mitch) Roob, Secretary of the Indiana Family and Social Services Administration

Kerry Weems, Acting Administrator, Centers for Medicare and Medicaid Services, and Vice-Chair, AHIC

Introductory Comments

Secretary Leavitt expressed his eagerness to see continued progress on the two parallel tracks on which the Community is operating. The first is the continued drive forward with the work already in progress; the second is setting up AHIC 2.0 to accelerate this work into the future. He reminded the Community that establishing the AHIC successor as a private-public collaboration within the private sector is a critical part of ensuring long-term sustainable IT environments for health care. This work should not be dependent on political prioritization or Congressional funding; rather, it needs to be an organic process that brings all of the relevant stakeholders together to find the solutions that the market will support. Secretary Leavitt acknowledged the aggressive set of deadlines to have AHIC 2.0 operational before the end of this year, and indicated that the Brookings Institution organizers are on track.

The Secretary then gave an update on the Electronic Health Record (EHR) Campaign—a demonstration project in which Medicare will reward a group of small- to medium-sized practices that use EHRs to improve the quality of the care that they deliver to patients. The Campaign will involve 1,200 practices and include about 3.6 million patients. He indicated that some private insurers have already signaled that they are willing to do parallel offerings on their own, which will rapidly multiply the effect and provide additional insight into how EHR adoption will work. Applications are due on May 13, 2008. Secretary Leavitt stressed that although only 12 grants will be awarded, the process of developing a proposal is valuable because it brings together community stakeholders to discuss these issues.

Mr. Weems echoed Secretary Leavitt's comments by noting the great fluency in communities around the country about AHIC. He commented that the work of this group is taking hold at the "grass roots" level.

Dr. Kolodner reported that a grant program associated with the Nationwide Health Information Network (NHIN) has made six awards. The entities that will be joining the NHIN Cooperative will participating in

trial implementations this fall. These entities include Bloomington Hospital, Cleveland Clinic, Community Health Information Collaborative, HealthBridge, Kaiser Permanente, and Wright State University.

Secretary Leavitt asked if NHIN demonstrations are still on track for September; Dr. Kolodner confirmed this, explaining that there will be trial data from two demonstrations.

AHIC 2009 Priorities and Use Cases

Dr. John Loonsk, Director of the Office of Interoperability and Standards, ONC, explained that his presentation would focus on the 2009 use cases under consideration as well as smaller projects termed "extensions and gaps." The concept is to have priorities ready to be processed through the Healthcare Information Technology Standards Panel (HITSP) and the other aspects of the national agenda moving forward as AHIC 2.0 ramps up. To date, 230 AHIC "needs and issues" were addressed in the 2006, 2007, and 2008 use cases, with nine left over. During the 2009 refresh process, an additional 149 needs and issues were advanced as either use cases or extensions and gaps.

Dr. Loonsk explained that the priorities that AHIC sets, via these use cases, are arrayed across the different activities of the national agenda. The use cases go to HITSP and come back as interoperability specifications, which Secretary Leavitt then accepts as the first steps of the process. There are currently 60 standards that are in this accepted status—these were advanced in January 2008 and will be recognized in January of 2009. A total of 52 standards have already been recognized in January of this year, and are moving to the next steps, which include implementation by the Certification Commission for Healthcare Information Technology (CCHIT) for use in federal systems and healthcare contracts, and also in the context of the NHIN.

A series of descriptions of possible use cases was disseminated to AHIC ahead of this meeting, each of which includes a brief explanation of the particular use case at hand as well as a series of quotes that describe the attributes of that use case. Each AHIC member was asked to identify three use cases for prioritization, and six to eight gaps or extensions. As part of the day's discussion, Dr. Loonsk wanted to confirm the group's top three use cases and ensure that the gaps and extensions were prioritized so that roughly six to eight of these can be implemented in conjunction with the three use cases and moved forward within the national agenda processes for 2009.

Secretary Leavitt indicated that there is a set of emerging events that may impact AHIC's recommendation. As the physician reimbursement debate moves forward in Congress, it is clear that one of the areas of interest is in compensating physicians and hospitals at the highest rate when they are reporting on quality measures. Given the fact that that debate is going to occur, and given the fact that there may be incentives that are linked to it, Secretary Leavitt suggested that AHIC contemplate how to make certain that the physicians have the tools necessary to make EHRs an economically viable proposition.

The Community reaffirmed the need to focus on "the basics" in terms of the 2009 agenda. They concluded that they will consider all of the items on the extensions and gaps list through number five as being basic gap fillers. The group also decided that it is still open to adding the Medical Home Care and Coordination "new" use case, if the argument can be made that working on that one also fills in a significant piece of the 13 existing use cases. Secretary Leavitt stated that there will be an expectation that AHIC 2.0 will utilize the priorities that the Community has established in the first period of their work. AHIC 2.0 will set their own work profile for the following year.

Discussion Highlights

"We are an awfully long way from the measures being able to be mechanized in any way…and there is no mechanism now to push a button and get the reason why something wasn't done easily expressed, so that it can be measured. We are probably years away from that, even if we got standards, because the measures are ahead of the standards, and it's not a simple yes/no question." – Mr. Kahn

"As we add use cases on to this system, it seems to me we're just building a bigger and bigger system with more and more capability…If we don't have a fundamental basic capability that everyone can use, and we keep adding requirements on to that faster than the base system gets built, where do we end up? This is kind of like building the next [operating system]. Eventually you have to start taking things off the table to get the operating system implemented, rather than adding more and more requirements on to the system." – Dr. Barrett

"To be sure that standards are implemented in systems, you have to test to them. You have to test with a fair amount of assurance. To do that, you need to have a very specific standard. To have a very specific standard, you need to have it set in a context. And that's the value of these use cases is basically for the standards people to look at these and say, 'Okay, we can argue about standards in a general way all we want, but in this specific context of this use case, this is the standard to use.' And that's what's being advanced through the queue." – Dr. Loonsk

"Whatever this body or others can do to grab the attention of the vendor community to more quickly embed this type of software programming…in electronic health records so that it becomes much more easy to report clinical data importantly back to the clinicians first, in terms of quality improvement of direct patient care, but also to others relative to pay for performance programs or whatever the case may be…the better." – Dr. Henley

"I am very concerned…that we are putting burdens on AHIC 2.0 before we've even let them get off the ground…I fear that we will spend time in 2008 working on things that may or may not get continued effort going into AHIC 2.0." – Mr. Hutchinson

"This prioritization will guide the development of use cases which, in an iterative process and with public comment, will take several months…Those use cases become the work that HITSP works on next year. In the absence of that, there are no use cases that go forward." – Dr. Kolodner

"There is enough work to be done in the previous use cases, these extensions and gaps. You could actually create probably a much bigger list of extensions and gaps on previous use cases that they could work on, versus adding more use cases." – Mr. Hutchinson

"We focused HITSP initially on harmonizing standards, but also trying to work through gaps. So one of the things that has not been prominent in their initial work is to work with [standards development organizations] in a really team fashion, to try to fill the gaps that are in some of these use cases. So there is gap work that could be done. But I'd also think that they have significant capacity, and the capacity they have will not be met just by continuing the work that they have been doing, that they, indeed, have capacity to add gaps and add extensions in the context of this year's work." – Dr. Loonsk

"You could add applications to the basics once you've got the basic infrastructure done. If you get the basic operating system with the basic engineer, and it's got open interfaces on both sides, then you can write applications to those interfaces. But if you try to write all the applications before the engine is done, you get nowhere." – Dr. Barrett

"Medical home and care coordination, maternal and child health, newborn screening, and long-term care and assessment are really specific to patients…what we've done before is a more broad-based review affecting almost all patients. These are very specific groups. And I'm not saying that's good or bad. It's just an observation." – Mr. Roob

"I can envision, my own sense, much more clearly, how maternal and child health, as an example, can increase the quality and quantity of human life in this country, much more easily than I can envision how consumer empowerment might." – Mr. Roob

"The thing, Mr. Secretary, that most closely addresses this issue you're bringing up, and frankly, equates to some of the discussions at HITSP as well, in terms of looking horizontally instead of looking vertically, would be to further develop these gaps and extensions as a way of trying to identify those basics." – Dr. Loonsk

"Certainly in the interoperability between VA, DoD, and between our other partners, filling in the laboratory and medication gaps is essential and those order sets, so we're not just viewing other people's information, but we can act on orders from outside of our system. Those would be a big priority for VA." – Ms. Graham

"I don't think there is anything more basic than focusing on the patients that are in the medical home, and the issue of care coordination. Now, obviously I have a conflict of interest to declare. I'm a family doctor, I'm a primary care physician, and I represent primary care docs…in connecting [patients] to primary care through this concept we now call the medical home, [there is] a body of literature that supports that that leads to better quality and cost efficiency, even in the absence of HIT. And it can only get better with HIT superimposed upon that." – Dr. Henley

"While theoretically I agree with you, pragmatically I will tell you, having tried to knit together several different medical home and care coordination organizations in the City of Indianapolis and the State of Indiana, it is a very, very nascent process. It doesn't exist." – Mr. Roob

"Last night, 13,000 people who were developmentally disabled were on waiver services in the state of Indiana, and about 25,000 people were in nursing homes. Those providers are doing care coordination. They are a disparate group. There are thousands of different organizations that are doing that. That's roughly 40,000 people in the state of Indiana, which is two percent of the nation's population, spending a huge amount of Medicare/Medicaid dollars. That care coordination is not connected in any way to their physicians. And creating an EHR won't help. It is about connecting the financing mechanisms, it is about really substantially changing the way care is coordinated." – Mr. Roob

"DoD and VA are, of course, doing significant work on care coordination around the wounded warrior. So we will or should have good products that touch on those issues that you're speaking of. Now, I can't speak to maturity of the industry, but we are going to be spending considerable funding in that area, which of course then those products would be available for the private sector to pick up. If we're looking at areas where we can take advantage of what's already going on…I think this is one area that we might want to pursue." – Dr. Jones

"You've got 13 use cases already…[In] those use cases and the infrastructure associated with them, how many of the 300 million Americans are covered? And I'd suggest that it's very, very small. And the basics has to get the 300 million Americans involved in this system, and the basic health care community involved in the system, and then spread that out. And then you can write applications on top of that. I just look at all the new use cases as applications you want to write on top of a basic infrastructure. The infrastructure is not there. We're deluding ourselves if we keep adding neat use cases on to an

infrastructure which can't support them…If, in fact, the facilities can't support the infrastructure, you don't get the application." – Dr. Barrett

"[One goal of] the use cases, as they have been advanced…is to identify those harmonized standards. Identify them with enough specificity they can be used in systems. That is the principle activity we have been engaged in here." – Dr. Loonsk

"Let's make sure that those 13 are implemented and that the gaps are filled, and that we can, then, build off of those going forward. Until those 13 get implemented, and used and spread around, I think it's inappropriate for us to add more on top of them. That's my only point. That's the basics, in my definition. Get those 13 done and used, and use your efforts in certification and filling gaps to make sure that those 13 work. Then we could build on top of them. But we're so far from getting those 13 fully implemented." – Dr. Barrett

"I think we ought to acknowledge that there is a whole series of the gap fillers that uniformly people are comfortable moving forward on…there are pieces of number 14 that can be considered gap fillers in a whole series of the other use cases. And that, therefore, there may be, in fact, a virtue to adding 14 because it fills in a bunch of the other things that we do. I'd like you to go back and look at that, and come back with us at our next meeting. But let's acknowledge that there are a series of the gap fillers that we can get you started on now, so that this month doesn't cost us at somewhere else, some other period in the pipeline." – Secretary Leavitt

"If something doesn't make it, I'm looking right at death reporting, because we're spending a lot of money, and soon to spend a lot more money on electronic death reporting as part of pandemic planning. Is there a consequence for delay? Will we regret that we didn't put a use case up when we know we have to be paying for expensive systems that will have to be altered or changed?" – Dr. Julie Gerberding

"It's a question of whether there is a harmonized standard for that purpose. There has been some work done in standard for a death report in HL-7, but not everyone has agreed to that specifically."
– Dr. Loonsk

AHIC 2.0 Successor Update

Dr. Mark McClellan, Director of the Brookings Institution's Engelberg Center for Health Care Reform, explained that AHIC 2.0 began with a grant from HHS to LMI Consulting, with the Brookings Institution providing substantive guidance with policy and technical expertise. The next step is anticipated to result in an independent, privately based public-private partnership that is focused, results-oriented, and inclusive, and with LMI and Brookings' role as that of a convener, trying to move along this process on an aggressive timetable while remaining open and collaborative. Dr. McClellan acknowledged that this process will not overcome every obstacle; rather, the group will identify some clear ways in which short-term and longer term progress can be made, and create a sustainable process to build upon.

Currently, the AHIC successor is half-way through the first of three transition phases, with stakeholders convening to help define the broad boundaries for planning and establishing AHIC 2.0. Over time, Dr. McClellan said, this transition process will move towards dependence on the successor organization itself, as it moves towards its fully operational phase. AHIC's successor has established a number of planning groups and a broad public input process. Dr. McClellan acknowledged that they have been lucky to receive significant participation from a broad range of stakeholders that have extensive technical expertise and leadership in health care. Four planning groups have been convened: (1) Organization Governance, (2) Membership, (3) Business Sustainability, and (4) Transition.

One issue tied to AHIC 2.0 that is consistently brought up in discussion is the need for clarity in terms of the scope and activities that AHIC 2.0 will be expected to undertake. Built into the first four months are a number of opportunities for anyone to provide input, including three public meetings. As the four planning groups continue, their work is expected to be increasingly coordinated with the specific activities of the successor (these activities will be defined by the four planning groups as well as continued dialog associated with the public input process). Based on public comment and the input process so far, interest is primarily focused in the areas of accelerating and coordinating the movement towards increased health IT interoperability, avoiding duplication of efforts in the process, and the importance of making specific, demonstrable steps towards making AHIC 2.0 a sustainable organization.

Dr. McClellan acknowledged the need to be very clear about the benefits of participating and supporting the effort, which likely will mean framing objectives not just as long-term broad national five-year goals, but also including specific milestones that can be accomplished in a more limited timeframe. This will keep people at the table and maintain both momentum and enthusiasm. Dr. McClellan also emphasized that health IT is but one element in a range of other issues that require work. Other tasks include efforts related to better measures of quality and cost, changes in payment to support better value, changes in coverage to support better value, and better evidence on what works. In short, the goal is connecting people to better health in terms of quality, safety, and cost.

Dr. McClellan noted that Brookings is hosting a series of listening events that will highlight concrete examples of health IT adoption. This "listening tour" was designed to bring stakeholders together to highlight opportunities for effective health IT adoption, and to identify specific short-term roadblocks to broader adoption and strategies for collaborative action to achieve widespread implementation. Examples of specific issues to be addressed in such meetings include chronic care improvement, e-prescribing, quality measurement, drug safety, and administrative simplification. Dr. McClellan closed his presentation by urging Community members to provide input on AHIC 2.0 by visiting the Web site www.ahicsuccessor.org.

Discussion Highlights

"We've got to be real careful that we don't come up with a business model that depends on dues as the primary source of income, because it will not work. It will consume the CEO, it will consume the senior staff, and there has got to be a business model where there is…something that keeps this thing going." – Mr. Kahn

"There may well be legislation this session or next session that has a big impact on some of the support and activities around for promoting health IT adoption. The AHIC successor needs to be able to respond and interact with those kinds of efforts, to be able to work with policymakers, but not making policy itself." – Dr. McClellan

"ONC was established to help move forward the achievement of this secure interoperable health infrastructure. I think the intent is not for the government to run that, but to foster it. And one of the things we talked about is that AHIC 2 isn't a privatization of the AHIC. It's a public-private entity." – Dr. Kolodner

"How can we make this handshake in the most effective way? Should we continue to fill the HITSP assembly line with priorities that AHIC 2.0 may not have fully adopted because AHIC 2.0 does not fully exist?" – Secretary Leavitt

"Over the course of the last couple months this has been up and running, we have gotten a long list of issues that we need to think about in the succession process. One set of those issues relates to exactly

this question of how should the hand-offs occur, and how much volume is going to be handed off in the process. The answer to that I think is going to shape up to be some—not too much, not too little." – Dr. McClellan

"I would like to make sure that we have a clear idea about what HITSP has in mind, what AHIC 1 has in mind for the successor activities, and [that] we have an opportunity to discuss that with the relevant Workgroups, and in particular I think the Transition Planning Workgroup, in the weeks ahead. And we both may need to modify a bit of what we're thinking. We may have one set of ideas based on our initial input that doesn't fully reflect all the appreciation for all the work that's ongoing. And conversely, as we learn more from the listening tour, and define more clearly scope and purpose and activities, we may need to modify the initial plans for HITSP." – Dr. McClellan

"The decision on this transition was made, and we're going to go through that process. And part of that is a bridge. We said we'll put money up to create the convener...so that there is a period of time in which it can operate while it develops its business model. But with that money, frankly, comes an expectation. And the expectation is that the new group is going to continue the work that we're doing…my own sense is there can't be an open-endedness on the first six months or a year of what AHIC 2.0 does." – Secretary Leavitt

"I'd like to see us continue the work of 1.0 as long as we have to, until we have a mature organization, or at least a coagulated organization that can then take what we've done, finish up what we started, and then create their own priorities to fill in at that point. In other words, I see 2.0 filling the HITSP chain next year, not this year." – Secretary Leavitt

"I think that's exactly the right general model for how this transition can occur." – Dr. McClellan

"I hope there will be a grant at some point that will come from HHS to whatever the successor organization is. Maybe it won't be 100 percent, but it's going to need to be some portion of it. We haven't got that money appropriated, but it will be a lot easier to get appropriated if the organization is up and functioning, and we can say 'here is the public good that's coming from it, and this is the budget, and we only need this much'." – Secretary Leavitt

"I would just reflect the concern that I hear from a lot of people that if this is a public-private partnership, much like this has been to date, I'm worried about the public side of it, in terms of who shows up at the table. Because frankly, in the two and a half years we have been doing this, the reason this effort, I think, has been successful has been due to [Secretary Leavitt] showing up, and your passion, and the heads of the major agencies showing up…Frankly, if those types of folks don't continue to show up and sit in the seats, rather than sending other folks, I have concern that 2.0, with all the money in the world, will not be successful." – Dr. Henley

"The process you're going through is a good one, but we've got to sort through all of the noise and get an organization, and get it into place, and let it begin to function, because it will begin to gel, once you get the organization there." – Secretary Leavitt

"The amount of leadership that has stepped up to the plate…really needs to be acknowledged when you look at the names on the planning groups, the tremendous breadth and depth of talent that's there really shows dedication to the cause." – Ms. Gelinas

"Transition Planning Group is in a place where we need to begin making a plan…we need two things. We need an accurate inventory of everything 1.0 has done, what the gaps are, and what reasonably we, as 1.0, can fulfill by the end of the year, and what's going to be handed off to the successor. We need that

badly. We need it accurate. We don't need something high level. We need something actionable." – Ms. Gelinas

"The reason we can come to the table and try to make informed decisions is because we're really well prepared…the sustainability of this somehow has to replace that, or else borrow it or formalize the ongoing relationship between the staff work that really makes this happen…I'm just not sure how the model for the new AHIC will be able to continue to guarantee that that level of capability goes with the new organization. Because we couldn't be successful without it." – Dr. Gerberding

"Just to push a little bit, I mean the fact that Secretary Leavitt is at the table, and the agency heads are around the table, really validates that reach, and motivates it in some pretty powerful ways…Hopefully, a new Secretary will want to be at the table as well. But if that doesn't happen, then we've got to figure out how to assure that there is the incentive and the hierarchical expectation of continued participation that goes behind good will on the part of leaders." – Dr. Gerberding

"It may be that the hand-off doesn't happen until the 21st of January, and it may be that when we get there, we realize we're just not ready for the hand-off. That would disappoint me. I think it would be less than optimal. But it's possible. And if it is, we need to have 1.0 continue to operate, and continue to do its work until the time for that hand-off has arrived. And so what I would like all of you to commit to is that we'll continue to work on AHIC 1.0 until the hand-off is ready." – Secretary Leavitt

Quality Workgroup Recommendations

Dr. Carolyn Clancy, Director of the Agency for Healthcare Research and Quality (AHRQ) and Co-Chair of AHIC's Quality Workgroup, began by stating that the broad charge of the Quality Workgroup is to make recommendations to the AHIC so that health IT can provide the data needed for the development of quality measures that are useful to patients and others in the health care industry, automate the measurement and reporting of a comprehensive current and future set of quality measures, and accelerate the use of clinical decision support that can improve performance on those quality measures. The group is also charged with making recommendations for how performance measures should align with the capabilities and limitations of health IT.

Dr. Clancy presented a slide highlighting a roadmap for developing HIT capabilities. Payment reform is clearly an accelerator for the transition, as are data exchange and aggregation.

The key themes from the roadmap are as follows:

- **Patient-centric quality measurement.** The patient-centric emphasis in the broad charge indicates a need for longitudinal quality measurement and improvement, where data is collected and used to inform quality improvement across care settings and over time, thereby putting the patient at the focal point of any improvement efforts.

- **Payment reform as an accelerator.** Payment reform is required to create incentives for both better-coordinated, high-quality health care and the development of a health IT infrastructure to enable the exchange of health information across care settings.

- **Importance of data exchange and aggregation.** Patient-centered care requires data exchange between providers and across care settings. Data aggregation is needed to create population-level metrics for the purpose of longitudinal quality measurement and improvement. Policy decisions and

industry consensus must be established in order to further develop existing strategies and technological solutions, which include, but are not limited to interoperable IT systems, protocols for physician and provider matching, and rules related to privacy and security.

- **Alignment around national priorities.** A national priority-setting process will focus the development of measures, the needed enhancements to medical coding, and the development of IT specifications and standards related to interoperability, data export, and storage that are necessary to allow efficient assessment of the nation's progress towards quality goals.

- **Proactive consideration of health IT needs to support quality.** The links between quality measurement and improvement and health IT need to be addressed proactively to achieve the future state of the vision. A common set of data elements (i.e., a quality data set) can be used across quality measure development, health IT standards development and harmonization, guideline development, and clinical decision support to facilitate better coordination.

- **Support for a hybrid data strategy.** Much of the work toward the future state vision can begin now; there is no need to wait for full electronic health record (EHR) adoption. A hybrid data strategy can make use of existing sources of data (paper-based and electronic, administrative and clinical) for quality measurement while also integrating increasing amounts of clinical data from EHRs as it becomes available.

Dr. Richard Stephens of The Boeing Company and Quality Workgroup Co-Chair, explained that the Workgroup tried to put together recommendations that begin to align three key elements that are critically important. These elements are: (1) all of the components of the roadmap are critical and will need to be addressed in order to achieve the vision; (2) although the scope of the vision roadmap is quite broad, the Quality Workgroup chose to focus on a few areas where substantive progress could be made within the next year and which have the potential to create a cycle of progress towards the eventual realization of the future state vision; and (3) many of the activities described in the recommendations should continue beyond the initial funding cycle. Therefore, funding models are needed to help sustain these efforts into the future, including the possibility of transition to the AHIC successor.

Dr. Stephens added that while the Quality Workgroup is primarily focused on datasets and the information technology, it is clear that these activities are about change management. Both AHIC 1.0 and AHIC 2.0 must consider and recognize the importance of change management and how to motivate changed behaviors. Otherwise, Dr. Stephens cautioned, there will continue to be quality datasets that are disparate and not integrated.

Dr. Clancy explained that in crafting its recommendations, the Quality Workgroup tried to focus on specific activities and steps that any set of leaders coming into AHIC in 2009 would believe were clearly indispensable to moving this vision forward. The recommendations are focused on improving the quality of data used for quality measurement and reporting by: (1) facilitating the alignment of initiatives to develop and implement quality measures, (2) developing and implementing a quality data set to support quality measurement and reporting, and (3) prioritizing the creation of standards for structuring selected clinical data.

The Quality Workgroup made the following recommendations in the following areas:

Facilitating the Alignment of Initiatives To Develop and Implement Measures for Quality Improvement

- **Recommendation 1.1:** HHS, including the Office of the National Coordinator for Health IT and the Agency for Healthcare Research and Quality, in coordination with the Quality Alliance Steering Committee and the AHIC successor, should convene forums at regular intervals through December 2008 in order to facilitate the alignment of quality improvement and health information technology initiatives; in particular, those initiatives supporting quality measure development and implementation. Representatives of specific organizations should be included in the forums, such as the Centers for Medicare and Medicaid Services, the Federal Health Architecture, NIH/National Library of Medicine, the National Quality Forum, HITSP, CCHIT, Integrating the Healthcare Enterprise (IHE), and the AMA-NCQA Collaborative. Additionally, representatives of organizations such as guideline developers, AQA, HQA, the Joint Commission, and standards development organizations (SDOs) may be invited. As an outcome of the forums, HHS, in collaboration with the represented organizations, should develop a plan by October 28, 2008, for continued public-private cooperation to align the initiatives.

Developing and Implementing a Quality Data Set To Support Quality Measurement and Reporting

- **Recommendation 2.1:** HHS, including the Agency for Healthcare Research and Quality and the Centers for Medicare and Medicaid Services, should collaborate with key private sector stakeholders, including measure developers, health IT vendors, clinicians, providers, and quality organizations, to define a quality data set that would support quality measurement that is automated, patient-centric, and longitudinal with the goal of improving care delivery and outcomes. The quality data set should include, at a minimum, relevant data captured during inpatient and physician office visits, and data required to support transitions of care among other provider settings.

- **Recommendation 2.1.1:** By December 31, 2008, the collaborative effort named in Recommendation 2.1 should review existing data sets used for quality measurement, including those developed by the Centers for Medicare and Medicaid Services for its CARE tool, by the HITEP in its initial work, by the Joint Commission for transfers of care, and by others as appropriate, as the basis of a harmonized minimum set of data types or elements that can be used for automating quality measures. The effort should also incorporate into the harmonized quality data set those data types or elements needed to support measure sets and national priority areas. The effort should assign a priority level to each data type or element within the quality data set as an aid to implementation.

- **Recommendation 2.1.2:** The Centers for Medicare and Medicaid Services, in expanding its set of quality measures, should work with the Indian Health Service to test the effectiveness of the harmonized minimum set of data types or elements, as developed in Recommendation 2.1.1, to capture and aggregate data from electronic health records.

- **Recommendation 2.1.3:** HHS, in coordination with the Quality Alliance Steering Committee and the AHIC successor, should maintain the minimum quality data set over time, modifying the quality data set as needed to address new measures and national priorities for quality measurement, and obtaining feedback on the quality data set from measure developers, health IT vendors, clinicians, providers, and quality organizations.

- **Recommendation 2.2:** Within three years following the identification of a quality data set, the Centers for Medicare and Medicaid Services should promote the use of the quality data set in its requirements for quality measurement and reporting across care settings.

- **Recommendation 2.3:** To accomplish some quality objectives, electronic health records must not only exchange data but also use and store certain data types or elements within electronic health

records. Therefore, the Healthcare Information Technology Standards Panel (HITSP) should identify the data standards needed to fill identified gaps for inclusion of the identified quality data set for use in both ambulatory and inpatient electronic health records.

- **Recommendation 2.4:** The Certification Commission for Healthcare Information Technology (CCHIT) should consider developing the appropriate criteria necessary to support the inclusion of the identified quality data set in both ambulatory and inpatient electronic health records. This requirement should be submitted for inclusion on the CCHIT Roadmap in sufficient time for implementation in 2010.

Prioritizing the Creation of Standards for Structuring Selected Clinical Data

- **Recommendation 3.1:** The Agency for Healthcare Research and Quality, in collaboration with the Office of the National Coordinator for Health IT and in consultation with NIH/National Library of Medicine, should conduct an environmental scan of current initiatives where electronic clinical data is being used to inform quality improvement initiatives in order to identify areas where data standards for structured clinical data are needed. Initiatives for review include, but are not limited to, the Better Quality Information to Improve Care for Medicare Beneficiaries (BQI) pilots and the Nationwide Health Information Network (NHIN) Trial Implementation sites. In preparing the environmental scan, which should be completed by November 30, 2008, experts could be convened from the BQI and NHIN sites that have experience in combining clinical and administrative data from multiple sources.

- **Recommendation 3.2:** The Agency for Healthcare Research and Quality, in collaboration with the Office of the National Coordinator for Health IT and in consultation with NIH/National Library of Medicine, should use the results of the environmental scan from Recommendation 3.1 as well as the work of the National Quality Forum's Health Information Technology Expert Panel (HITEP) to develop recommendations to the Healthcare Information Technology Standards Panel (HITSP) for the identification of standards for structuring clinical data. These recommendations should be submitted to HITSP by January 31, 2009.

- **Recommendation 3.3:** Through its convening function, the Agency for Healthcare Research and Quality, in collaboration with the Office of the National Coordinator for Health IT and in consultation with NIH/National Library of Medicine, should produce an action agenda by March 31, 2009. The action agenda should prioritize areas for structuring selected clinical data used across care settings, and identify opportunities to align efforts that are already underway to create standards related to clinical data. This work should be guided by an expert panel comprised of members of the EHR vendor community, clinicians, providers, specialty societies, standard development organizations, the National Quality Forum, guideline developers, measure developers, health plans, the Quality Alliance Steering Committee, the AHIC successor and others as appropriate, to ensure that standardization of documentation is aligned with care delivery and the development of executable guidelines and automatable quality measures.

Discussion Highlights

"There is a huge transition in getting from the quality measures we have now to the priority process that NQF has launched, which I think is very exciting. But they are going to be coming up with measures that either need to be developed or are developed, but for which there are not clinical data standards right now. That's where the quality dataset comes in. It's not upending that process at all. They have convened all the right stakeholders, and I think are going through a terrific process to say 'what are the big priority items?' One of them is hospital mortality, for example. Another is healthcare-associated infections.

Another is a very broad look at population health. So there are exactly, I think, the right level of priorities. But this would actually make that possible. Absent that, they are great ideas. It's a great set of ideas, but this would operationalize it." – Dr. Clancy

Following these comments, all of the recommendations put forth by the Quality Workgroup were accepted by consensus, with an amendment to add a reference to the Department of Veterans Affairs (VA) and the Department of Defense (DoD) to Recommendation 2.1.2.

Confidentiality, Privacy and Security Workgroup Recommendations

Mr. Kirk Nahra of Wiley Rein LLP and CPS Workgroup Co-Chair, explained that his comments focus on revisiting a recommendation that had previously been discussed about participants in health information exchange (HIE) networks, as well as the networks themselves, being held to a standard that is at least as high as the Health Insurance Portability and Accountability Act (HIPAA) standard.

The recommendations are as follows:

- **Recommendation 1.0:** The obligation to provide "individual rights" and a notice of privacy practices under the HIPAA Privacy Rule should remain with the health care provider or health plan – who today has an independent relationship with a patient or consumer – and not an HIE. The CPS Workgroup recommends that health information exchanges (HIEs) and regional health information organizations (RHIOs) (collectively referred to in this letter as HIEs) that do not have "independent relationships" with patients or consumers be exempt from meeting the following HIPAA Privacy Rule requirements:
  - §164.520 Notice of privacy practices for protected health information;
  - §164.522 Rights to request privacy protection for protected health information;
  - §164.524 Access of individuals to protected health information;
  - §164.526 Amendment of protected health information; and
  - §164.528 Accounting of disclosures of protected health information.

- **Recommendation 1.1:** HIEs should make publicly available on their website (or through other means) a document that reasonably and accurately describes in plain language how they use and disclose health information and their privacy policies and practices, as well as how they safeguard patient or consumer information.

The Community adopted the recommendations by consensus.

Discussion Highlights

"The question was whether we were going to add a new responsibility for the health information exchange, itself, and we said HIPAA rules will apply to those exchanges unless we say something was relevant. So everything applied except for the few on our list where we said we didn't see any point in having the health information exchange send its own privacy notice out: not the doctor's notice, not the hospital's notice, but create its own notice, and then send it out to individuals simply because their information flowed through the database. If we had not taken that step, you would get a notice from something called health information exchange that you, as a consumer, probably never heard of, never signed up for, didn't choose, didn't have anything to do with, and we just thought that was an unnecessary expense, confusing, et cetera." – Mr. Nahra

Following discussion, both of the recommendations put forth by the Confidentiality, Privacy, and Security Workgroup were accepted by consensus.

Clinical Decision Support Workgroup Recommendations

Dr. John Glaser of Partners HealthCare and Co-Chair of the Clinical Decision Support Ad Hoc Workgroup began with a reminder about the purposes of clinical decision support (CDS) and the work of the CDS Workgroup, explaining that the use of CDS capabilities within EHRs and related electronic clinical systems holds great potential to improve health care outcomes in the United States. CDS provides clinicians, staff, patients and other individuals with knowledge and person-specific information, intelligently filtered at appropriate times, to enhance health and health care. In addition, CDS is inherently cross-cutting and engages several AHIC Workgroups.

Dr. Glaser noted that the three objectives of the CDS initiative are to: (1) advance patient-centric care and improve health care outcomes through effective use of CDS, (2) accelerate the successful adoption of CDS in a wide variety of health settings, and (3) enhance patient participation in care through thoughtful applications of CDS. He reminded the Community that ONC commissioned some work done by the American Medical Informatics Association (AMIA) that led to the CDS roadmap, which was published and presented to AHIC in the summer of 2006. In May of 2007, that group indicated to AHIC that it would like to continue with the work, and at that time formed the *Ad Hoc* CDS Planning Group, made up largely of members from across the other AHIC Workgroups.

Dr. Charles Friedman, ONC and CDS Workgroup Co-Chair, explained that the group discovered, as part of its planning process, that a great deal of activity was already ongoing across a number of government agencies with regard to CDS. This activity engaged these agencies in at least three roles: (1) as a direct employer of CDS systems for those agencies that are delivering health care; (2) as a funder of research and development activities; and (3) as a facilitator of clinical physician support by virtue of policies that these agencies were developing to catalyze the use of CDS, perhaps in other settings. The CDS Workgroup formed a cohesive but rather informal organization and termed it a "collaboratory," with the goal of synergizing the activities of these disparate agencies. The initial meeting of the CDS Collaboratory occurred in March; and the group will be meeting quarterly, face to face, beginning in June 2008.

Dr. Glaser then presented the CDS Workgroup's recommendations:

Drive Measurable Progress Toward Priority Performance Goals for Health Care Quality Improvement Through Effective Use of CDS

- **Recommendation 1.1:** Guided by the efforts of multiple national priority setting efforts (e.g., National Quality Forum's National Priority Partners Committee), representatives of federal agencies, including "the CDS Collaboratory", should identify priorities for federally funded CDS efforts by December 30, 2008. These priorities should consider existing government funded programs such as pay for performance, research and development grants, public health, and personalized health care. The CDS Collaboratory should develop an evaluation plan to monitor the impact of federally funded CDS programs on high priority areas. The CDS Collaboratory should widely disseminate its list of top priorities for CDS efforts, and how the government's CDS activities are helping to address those priorities.

- **Recommendation 1.1.1:** HHS should collaborate with AHIC, the AHIC successor, the Healthcare Information Technology Standards Panel (HITSP) and other organizations to identify and harmonize data types needed to support CDS tools, with particular attention to tools and use cases that address the high priority conditions determined by national priority setting efforts such as the National Quality Forum's National Priority Partners Committee.

- **Recommendation 1.2:** Once the priorities and evaluation plan from Recommendation 1.1 have been completed, the CDS Federal Collaboratory should facilitate alignment of CDS efforts, methods and metrics within federal agencies that deploy, support or facilitate CDS. The CDS Collaboratory should establish a mechanism to periodically measure the contribution of CDS efforts to accelerating progress within these agencies towards improving the care delivered for patients with the targeted clinical conditions.

Explore Options To Establish or Leverage a Public-Private Entity To Facilitate Collaboration Across Many CDS Development Activities

- **Recommendation 2.1:** By October 31, 2008, HHS and relevant partners should explore options to establish or leverage a public-private entity (e.g., AHIC 2.0 or other) to convene public and private organizations and stakeholders to promote effective CDS development and adoption and address gaps in CDS capabilities through planning, facilitation, and coordination of activities across diverse constituencies. The public-private entity could incorporate the viewpoints of multiple stakeholders by including representation from the CDS *Ad Hoc* Planning Group, the Certification Commission for Healthcare Information Technology (CCHIT), the Healthcare Information Technology Standards Panel (HITSP), the CDS Government Collaboratory (*ex officio* government representatives) and organizations that represent consumers, providers, payers, guidelines developers, medical informatics experts, life sciences, public health, clinical information system and CDS developers, and others.

- **Recommendation 2.2:** The public-private entity, working with its stakeholders, should plan a CDS infrastructure to serve the nation in the long term, and identify actions that its constituents can take to further the adoption of CDS. Looking across existing efforts within the public and private sectors, the public-private entity should identify approaches where coordination, collaboration and collective action can advance effective use of CDS.

  Elaborating on the kinds of activities that would be coordinated by this public-private entity, Dr. Glaser suggested that activities and deliverables may include, but are not limited to the following: (1) describe a model repository or repositories that will support the aggregation of readily-accessible, reusable, computable knowledge, decrease duplication of knowledge management efforts, and promote broader utilization of CDS; (2) describe mechanisms that can be employed to ensure that consumers and health care professionals can be confident that the knowledge algorithms behind CDS applications provide solid, quality suggestions and advice; and (3) develop a framework to optimize the delivery of CDS interventions so that advice is delivered at the right time, place and in a manner that enables consumers and health care professionals to act upon it in a timely manner.

Accelerate CDS Development and Adoption Through Federal Government Programs and Collaborations

- **Recommendation 3.1:** The Agency for Healthcare Quality and Research (AHRQ) and National Institutes of Health (NIH) should support additional research to enhance discovery and application of best practices for utilizing clinician-specific and patient-specific CDS tools supportive of decision-making in EHR and Personal Health Record (PHR) systems by September 30, 2009.

- **Recommendation 3.2:** AHRQ, Centers for Disease Control and Prevention (CDC) and NIH should support additional research to identify CDS approaches and interventions that patients in chronic disease groups such as diabetics, and other special populations, are most likely to use and find helpful when managing their own care by September 30, 2009.

- **Recommendation 3.3:** To facilitate inclusion of consumer preferences in systems that support collaborative patient-provider decision making, HHS, through appropriate funding mechanisms, should support the development of a minimum data set of personal attributes that contribute to individualized care by June 30, 2009, expanding on existing work, such as that of the National Quality Forum's Health Information Technology Expert Panel. (Example attribute categories include: demographics, clinical history, and psychosocial factors.) Once the minimum data set has been created, HITSP should develop interoperability standards for the personal attribute minimum data set so that guideline developers and EHR vendors can produce and work with clinically consistent data. These interoperability standards should be added to the criteria for certification of Electronic Health Records (EHRs), as well as for certification of Personal Health Records (PHRs) at such time as those criteria may be developed.

- **Recommendation 3.4:** The Centers for Medicare and Medicaid Services (CMS) and Agency for Healthcare Research and Quality (AHRQ) should collaborate to ensure that there is a process by which Pay for Performance, and Pay for Reporting initiatives inform the design and content of future model CDS knowledge repositories, so that resulting repositories meet the needs of Medicare Part A and Part B payment updates involving specific quality measures on an ongoing basis. Additionally, a process should be put in place to ensure that future relevant EHR demonstration projects include CDS, and that CDS "lessons learned" are included in demonstration project reports.

The CDS *Ad Hoc* Planning Group will continue to serve as a planning group for CDS as a timely, cross-cutting area of AHIC concern. Current and future CDS Federal Collaboratory Activities will include the following: (1) serve as an implementation arm for AHIC recommendations on CDS, (2) share information about current activities in the field of CDS across the government, (3) identify opportunities for cross-agency and cross-department CDS collaboration, and (4) host educational events where members can learn more about cutting-edge CDS activities ongoing in the government and elsewhere

Discussion Highlights

"Certainly all can see the benefits of clinical decision support, but wouldn't this, perhaps, be a way that individual products might differentiate themselves in the marketplace rather than this body [AHIC] making a decision about them here?" – Mr. Weems

"What is on the table is taking our collective efforts, both those around the table and those in the private sector, and helping us learn from them and advance them. It is not also *per se* a standardization harmonization effort. It is really to take this class of technologies and improve our ability to apply them. That may lead to certification, although that's not *per se* what we are advocating here." – Dr. Glaser

"Have you considered whether or not what's going on might be building something competitive to the commercial market that may be building similar systems, or is this more content than [a] technology build?" – Mr. Hutchinson

"What you don't want to do is take on the market where the market is doing a great job. And so that's why I think you ought to get them in the room with a variety of things and say 'listen, how do we work with you guys?' Now, research on effectiveness benefits us all. Even if I turn around and get it from

informatics, or whoever I get it from, we're all better off as a result of that activity here. I think there are, in effect, a lot of decision support rules, which are more or less in the public domain, because they are published by the American College of X, who puts these things out here. If you had a source where you could get them all, rather than have to go here, and then here, and then there, it's not clear to me [that] we're undermining the free market in that regard." – Dr. Glaser

"There are also some very, very deep, fundamental problems relating to implementation of clinical decision support that have, for several decades now, defied solution. And I think that's because they are very, very hard, such as how to take a clinical guideline in verbal form and make it computable so it can be the basis of an effective and functioning clinical decision support system. I think a lot of these recommendations have their eyes on solving those fundamental problems, which if solved will be a resource to the entire nation going forward in this area." – Dr. Friedman

Following this discussion, all of the recommendations put forth by the CDS Workgroup were accepted by consensus.

Consumer Empowerment Workgroup Recommendations

Dr. Karen Bell, ONC, explained that since the last time Consumer Empowerment (CE) Workgroup recommendations were brought to AHIC, the Workgroup has been addressing the needs of specific populations that may have more intense or specific needs with respect to their health and care. One such community is that of the disabled. Another is the underserved. The underserved, Dr. Bell said, includes individuals who do not have adequate access to health care services. They may be poor, uninsured, have limited English proficiency, lack familiarity with the health care delivery system, or they may live in locations where providers are not readily available to meet their needs. Members of ethnic and racial minority groups are not by definition underserved, but are disproportionately found among their numbers.

She explained that the CE Workgroup's recommendations would be presented in two batches—those representing the needs of the underserved, and those representing the needs of the disabled. For purposes of these recommendations and any ensuing discussion, the CE Workgroup used the most recently evolved concept of a personal health record, defined as a platform that can securely store as much as a lifetime's worth of persistent data from many sources, and assure appropriate authentication and access under the patient's control. It can also interface with any one of a number of applications still being developed by the marketplace, which can make that data easy to access, understandable and useful to the consumer.

Persons With Disabilities

Dr. Bell then presented the recommendations related to persons with disabilities:

- **Recommendation 1.1:** HHS should coordinate activity to ensure that PHRs sponsored by the federal government are consistent with statutes and regulations, including accessibility standards in accordance with Section 503 (29 U.S.C. § 793), 504 (29 U.S.C. §794) and 508 (29 U.S.C. §794d) of the Rehabilitation Act of 1973 (Pub. L. 93-112).

- **Recommendation 1.2:** As HHS develops a use case with attendant interoperability standards specific to the needs of persons with disabilities, this use case should include the following:
  - Provision for coordinated care across multiple health care encounters, providers, and caregivers.
  - Access to and assimilation of information currently existing in paper format.

  - The ability of authorized care and service providers, including the Social Security Administration (SSA) and other public and private entities that have purview over disability compensation, to utilize electronic authentication and electronic transmittal to obtain relevant information from the PHR on behalf of the authorizing consumer or surrogate, in accordance with the authorizing parties restrictions on what data can be seen or accessed from the PHR.
  - Functional assessment for use by persons with disabilities in subsequent disability record development.

- **Recommendation 1.3:** As PHRs are certified, HHS should coordinate efforts to ensure that relevant electronic health information in these PHRs is interoperable with that in CCHIT certified Electronic Health Records.

- **Recommendation 1.4:** Any PHR offered directly or sponsored by HHS should be developed to accommodate technological applications that can be used by persons with disabilities, and can address accessibility issues that include differences in language, the broad range of racial and cultural diversity, and differences in family and community practice.

Discussion Highlights

"Does this mean that if you had a PHR, that you'd have to have voice-to-text, text-to-voice, to accommodate someone who's visually impaired? Or you would have to have text-to-text translation for a different language speaker?" – Dr. Barrett

"The PHR would have the ability to take in interoperable information and then interface with an application that would have the ability to make those kinds of translations." – Dr. Bell

"I support the goals, but I have some concerns about what it might mean for some of the demonstration type projects, and some of the more nascent work that we're doing and I think that some of our federal colleagues will be doing. And I'd hate for it to chill that effort before we could get some of these standards in place." – Mr. Weems

"The question becomes how should this be brought forth so that it is clear this is a goal, and what steps would be taken to get there? I clearly do not want to chill any efforts that are moving in this direction. But I think it's important for everyone to be cognizant of the fact that there is a community there that will need to have this information be made available to them in a way that they can use it, at some point." – Dr. Bell

"While I think the work here is terrific, and I deal with these populations every day, the nascent nature of the integration between health care providers and care coordinators is such that I think this will have exactly the effect you don't want it to have. I think we'll have a chilling effect on progress in an incredibly fragile delivery system at this point in time…it would delay efforts that we will make in 2009 to do something like this with our disabled population. And I'm not happy about that." – Mr. Roob

"If I could just comment at different levels here, because I think we're talking at different levels in terms of actions. At one level, which was passed over quickly but is important, is on the issue of disability benefit determination. And at that level, SSA now spends $500 million a year chasing medical records. And we heard from individual groups, such as Mass General, that gets 35,000 requests for medical records a year. And that's highly inefficient today. And the ability to do more of that electronically would bring efficiencies and reduce inefficiency in the system, relatively immediately." – Dr. Horan

"Then moving down to the issue of the lifetime record and CCIT, what we heard was many who have disabilities are already obtaining a lifelong medical record, and the existing products can't be in service to that. And then the third level, which is the level I think you spoke of before, which is the care coordination level: that care coordination level is highly fragmented, diverse, not in an IT savvy mode. I would agree with you that within that sphere right there, it is very much emergent and not at the ready." – Dr. Horan

"Because VA already falls under the 508, 504, 503 standards, for new development for a PHR, we had to comply with those standards. So My Health*e*Vet does comply with those standards today." – Ms. Graham

"My suggestion would be to take out the particular allusions to the federal government here so that HHS should coordinate activity to ensure that PHRs are consistent with statutes and regulations, rather than, perhaps, binding our hands, especially at such a nascent stage." – Mr. Weems

Following this discussion, the Community accepted by consensus all the Consumer Empowerment Workgroup recommendations referring to the needs of the disabled, with amendments to Recommendations 1.1 and 1.4 that strike reference to the federal government.

Racial and Ethnic Communities/Underserved

Dr. Bell then presented the following recommendations relating to racial and ethnic communities and the underserved:

- **Recommendation 2.1:** HHS should increase access for racial and ethnic minorities, persons with disabilities, and the underserved to health care delivery systems which are supported by health IT by specifying language referencing the inclusion of racial and ethic minorities, persons with disabilities, and the underserved in relevant contracts, grants, cooperative agreements, demonstration projects, and pilots which support the adoption of health IT within the delivery system.

- **Recommendation 2.2:** HHS, through the Office of Minority Health, shall lead the process of conducting an environmental scan on HIT use by medically underserved populations.

- **Recommendation 2.3:** HHS should pursue partnerships with private sector leadership to foster better communication between patients and providers in underserved areas via secure messaging, tele-health/tele-medicine, and remote monitoring in multiple settings.

- **Recommendation 2.4:** The Office of Minority Health (OMH) should work with ONC to leverage support for public/private and non-profit partnerships in efforts to market, educate, and increase usage of information technologies by racial and ethnic minorities to reduce health disparities. OMH, working with ONC, should take leadership in communicating about PHRs, their applications, and their benefits to community-based organizations by developing an action plan, timetable and metrics for the implementation of an education outreach plan.

Discussion Highlights

"As a goal, I support all four. Obviously this is something that needs to be addressed and should be addressed. My concern is if this is not a little out of scope for what we as AHIC are chartered to do, which is to really focus on the interoperability of health care, and some of this is not necessarily policy,

but it starts getting really close to making some recommendations on what HHS should be doing in these particular areas, which I don't really think is in the scope of AHIC." – Mr. Hutchinson

"One of the things that's of concern to AHRQ in disparities in health care is that as you move forward in the automation, we don't want to do anything to increase that disparity…the intention is to make sure that there is some continued effort to get that interoperability to help all individuals." – Dr. Kolodner

Following this discussion, the Community accepted by consensus all of the Consumer Empowerment Workgroup recommendations referring to racial and ethnic groups as well as the underserved.

Key Roles for State-Level Health Information Exchange Initiatives

Lynn Dierker, Project Director for the state-level HIE consensus project held by contract with the American Health Information Management Association (AHIMA), noted that this initiative began in 2006, targeting state-level HIE efforts (not to be confused with state government efforts). Ms. Dierker explained that 13 states are being represented in an iterative process of field research and consensus development, looking particularly at organizational dimensions of state HIE and how it is being organized at what used to be known as state-level regional health information organizations (RHIOs) and are now referred to as state-level HIE entities.

This group presented to AHIC approximately 1 year ago to discuss a report indicating that at the state level, these entities were organizing and carrying out important functions. The report pointed to several issues about the work that was happening at the state level to organize HIE and issues related to its growth and sustainability. Ms. Dierker noted that the group has found that there is continued expansion and evolution in state-level HIE efforts. For example, 75% of states have established state-level HIE initiatives/governance entities. Additionally, advanced state-level efforts are poised to begin data exchange; health care reform, privacy rights, and confidentiality protections are drivers of these efforts.

Ms. Dierker and colleagues are seeing continued growth and progress at the state level in organizing and becoming involved in—more and more states are getting involved as a way to address health care reform goals. She emphasized that there is a migration to two distinct and key organizational HIE roles at the state-level. First, in terms of the governance role, there are activities related to: (1) neutral convening (a structure for engaging stakeholders in a statewide mission to build HIE for health care quality and cost-effectiveness); (2) coordination (a mechanism to facilitate collaboration across diverse interests); (3) development and implementation of a statewide HIE roadmap; (4) consensus-based HIE data sharing policies and practices to ensure confidentiality protections; and (5) facilitating lowest cost HIE development serving statewide stakeholders. Secondly, in terms of technical operations, there are state-level technical functions (owned and/or managed) to facilitate statewide HIE as well as variable technical models and approaches under development.

Ms. Dierker then discussed the importance of state-level HIE governance. The state-level HIE governance role is primary and ensures that HIE develops as a public good (e.g., beyond silos, corporate interests), serves all statewide stakeholders and data needs, and reduces technology investments and other costs for all participants. The state-level HIE governance entity is a public-private partnership entity that: (1) sits between state government and the health sector and industry, (2) involves state government but is independent of state government, (3) addresses public and private-sector interests and blends investments, and (4) is a mechanism for coordination of HIE policies and practices. State governments also play important roles, such as designating authority to a state-level HIE governance entity, providing resources (both start-up and ongoing), and leveraging public programs as well as policy levers to create incentives

for HIE. Ms. Dierker explained that statewide technical approaches can vary and will likely evolve in terms of size, market characteristics, resources, and stages of development.

The ongoing work in the states suggests certain implications for AHIC; Ms. Dierker presented the following priority recommendations:

- Establish a permanent AHIC entity that is sufficiently inclusive and empowered.

- Develop an agenda to link strategies for HIE development with the health care transformation agenda (focusing on secondary use, quality, transparency).

- Foster synergy between nationwide and state-level HIE governance
  - Include state-level HIEs as key stakeholders in the permanent AHIC entity
  - Design a formal mechanism for state-level HIE participation.

- Ensure public-private state-level HIE entities are engaged in all aspects of AHIC work
  - Reflect HIE readiness across diverse statewide environments
  - Incorporate all state-level perspectives in its mission and activities
  - Serve as vital laboratories for informing, vetting, and advancing AHIC priorities.

Ms. Dierker noted that states have historic roles when it comes to consumer protection, involvement, and health—they represent populations of people and link to policy, legislation, and to the power of markets and private sectors. Therefore, this governance structure and function is an important and distinct role at the state level that needs to be in place. She commented that the group's aims for privacy and security protections will never be carried out unless there is a dedicated resource that can convene and coordinate the diverse entities and organizations doing this work, and get them to agree on data-sharing arrangements. Ms. Dierker expressed the hope that the group will be actively involved in the AHIC 2.0 design and implementation. She likened the states to laboratories that are a model for the Community's work

Rachel Block of the New York eHealth Collaborative (NYeC) then discussed her organization, noting that it is an independent, nonprofit, state-level HIE governance entity primarily focused on policy, consensus, and coordination activities. She explained that the Collaborative works with a host of organizations that are in the midst of procuring technical services to try to coordinate their activities. The building blocks for New York's health IT strategy include: (1) promote collaboration at state and regional levels, (2) support development of RHIOs, (3) link to national strategy and standards (focus on interoperability), (4) use infrastructure to expand reach, (5) privacy and security are essential to public trust, (6) support strategic uses of health IT (high-yield benefits from reducing inappropriate utilization and increasing use of preventive services), and (7) sustainability hinges on payer involvement. The goal of the NYeC is to galvanize health care systems' improvement by promoting broad use of health IT through a comprehensive and coordinated state policy agenda that:

- Stimulates coordinated and collaborative efforts among health care stakeholders to identify and overcome barriers to widespread HIT adoption and use to enhance evidence-based practice by clinicians, as well as consumer engagement in health maintenance and management.

- Advances health care performance measurement, public reporting, and improvement supported by HIT.

- Improves public health through effective prevention and management of chronic disease, as well as stronger public health surveillance and emergency response capabilities.

- Ensures accountability by measuring and evaluating HIT impact on health care systems, payers, providers, and consumers.

There are a variety of tools being used to implement the New York Health IT strategy, including coordinated policy leadership at the state-level through the State Department of Health. The NYeC itself was established to drive collaborative implementation efforts. The Health Care Efficiency and Affordability Law for New Yorkers (HEAL-NY) provides grants for state and regional initiatives promoting HIT and HIE. In addition, the New York HISPC is forging stakeholder consensus on policies and procedures to protect privacy and security, and ensure consumer access and engagement. Another tool is the Health Information Technology Evaluation Collaborative (HITEC) is a statewide academic consortia partnering with stakeholders and RHIOs to standardize evaluation measures and methodologies.

Ms. Block noted that HEAL-NY will provide $250 million over a 5-year period. She explained that this commitment is within the context of a $1 billion investment, which the state legislation approved several years ago, to try to provide capital support to stimulate needed health care system changes. The $250 million is specifically dedicated to HIE and HIT.

A statewide academic consortium has been established to coordinate all of the evaluation activities, standardizing measures, and methodologies across the entire spectrum of activities. Given the significant state investment and private investment in HIT projects, putting a priority on evaluation was a very important issue, and one that will ensure progress is achieved in a coordinated and collaborative fashion. Ms. Block presented an organizational chart of the New York eHealth Collaborative Board, showing the direct relationship between the Health Department and the eHealth Collaborative as well as connections with a number of strategic partner initiatives, the Business Council of New York State, the academic community, and a newly created consumer advocacy coalition to help stimulate more capacity-building among consumer groups so that they can participate directly in this policy discussion. The group's collaboration priorities include statewide and regional governance; technical requirements for interoperability; and components to sustainability, such as the value proposition at the clinician and consumer levels, continued investment in infrastructure, and ensuring trust through affirmative consent and privacy protections.

Ms. Dierker acknowledged that states have a "starvation diet" of resources, and that with any discussion of health IT, there are capital investments on the front end. New York is fortunate, but there are many states with small populations that are struggling to come up with programs based on their particular marketplace or their particular state budget. She concluded by noting that their project means to add value to the Community's work by presenting these issues, and by serving as a laboratory and a resource, with experts who grapple every day with these state-level issues, and who sit not only between state government and the industry, but between the state and national levels.

Discussion Highlights

"What's the most important thing AHIC can do for you?" – Dr. Barrett

"Involve us in your design and consideration in terms of how you deploy your priorities. Hear from this reality." – Ms. Dierker

Public Comment

Speaker Number 1—Carol Beckford of the American Nurses Association, suggested that the NCQA and the eHealth Initiative were missing partners in the conversation being had by the Clinical Decision Support *Ad Hoc* Planning Committee. She also suggested this group was heavily weighted to HHS, but did not appear to include the National Library of Medicine as one of the participants, or the National Center for Health Statistics. Further, she suggested adding the Department of Justice, particularly their Corrections Divisions, and their health care services in that environment. She also named DoD and VA as appropriate agencies to include in the discussion. Ms. Beckford also asked whether there has been an examination of the role of health IT in the international community. She emphasized the need to include all health care professionals, and not just physicians, in these discussions.

Speaker Number 2—Ruth Perot of Summit Health Institute for Research and Education, who has been a presenter for some of the sessions of the Consumer Empowerment Workgroup, commented that the recommendations made throughout the meeting were on target and expressed enthusiasm that they were received by the Community.

Speaker Number 3—John Donnelly, who heads a consulting business in healthcare IT, offered his compliments on the collaborative information that was presented at the meeting. However, he noted that he did not hear mention about improving the awareness of the consumer. There are many activities underway to facilitate consumer engagement in the health care process; efforts are needed to raise consumer awareness about what initiatives are underway that could affect them.

Before Mr. Weems' closing remarks, Mr. Roob requested that an upcoming AHIC meeting include a presentation or presentations from some of the PHR vendors who could describe their experiences and progress.

Closing Remarks

Before adjourning the 21st meeting of the AHIC, Mr. Weems thanked the Community members, speakers, and participants for their attendance and participation.

Department of Health & Human Services
Office of the National Coordinator for Health Information Technology

American Health Information Community

AHIC Successor Update

Mark McClellan
Engelberg Center for Health Care Reform
Brookings Institution

June 3, 2008

Opportunities for the AHIC Successor

- Phase I of the convening process is reaching conclusion, with recommendations coming tomorrow
- Phase II will lead to an organization that will embody the recommendations from the convening process
- The new organization cannot be sustained by dues alone – it must have a sustainable business model through which public and private partners can drive practical, relevant standards identification and harmonization in the future
- The process for establishing the new organization will continue through Phase II

The Successor design maximizes momentum

Building strength and momentum during the transition

Current AHIC Strengths	Expected Successor Strengths
• Effective at bringing the various stakeholders to the table • Strong leadership and commitment • "Marquee" factor • Clear demonstration of government commitment to effort • Success in driving results in the areas of standards and certification	• Scope that builds on current momentum • Members empowered and resourced to implement recommendations • Transparent Board of Director (BOD) and committee member selection process • Broad stakeholder representation in decision-making • Ability to focus increasingly on added value in promoting adoption of effective health IT

Stakeholders will engage in priority-setting through value cases

- A sustainability model based upon Value Cases holds promise for the organization's continuity into the future
- The standards identification / harmonization, and certification processes should be driven by market demand
- Private sector resources can fund this public-private partnership provided the value is there and there is broad stakeholder support
- This process will drive practical, relevant interoperability faster, ultimately improving the quality of health care and serving the public good

Setting strategy and priorities will be value-based

- Health Information Roadmap provides the context for priority-setting
- Value Cases developed by health care stakeholders lead to proposals for priority initiatives
  - Will allow for broad stakeholder engagement in priority-setting
  - A framework and criteria will be used to evaluate and select Value Cases
- BOD represents the stakeholder community, including consumer advocates and government
- Cyclical decisions use value-based criteria
- Funding of priorities aligned with value added
- Standards align with federal privacy and security policy

The Successor design minimizes potential risks

Potential Risks	Mitigations
• Reduction or elimination of federal funding	• Flexible funding streams based on dues and value of specific activities to stakeholders to support self-sustained entity
• Dilution of nationwide focus through multiple, similar efforts	• Inclusive public-private BOD composition with dedicated government and consumer representation, to achieve progress not otherwise possible
• Membership attrition insufficient to sustain the organization	• Value proposition will reach every member segment
• Marginalized authority over harmonization and certification priorities	• Strong ties to HITSP and CCHIT and on-going federal government participation at the BOD, committee, and operational levels to ensure a focus on practical, relevant interoperability

Passing the Baton

	2006	2007	2008	2009	2010
AHIC Round 1	• HITSP Publishes Interoperability Specification • HHS Accepts	• Industry Tests	•HHS Recognizes •Certification		
AHIC Round 2	• AHIC Selects Priorities • ONC Develops Use Case	• HITSP Publishes Interoperability Specification	• HHS Accepts • Industry Tests	•HHS Recognizes •Certification	
AHIC Round 3		• AHIC Selects Priorities • ONC Develops Use Case	• HITSP Publishes Interoperability Specification	• Industry Tests	•Certification
AHIC Round 4			• AHIC Selects Priorities • ONC Develops Use Case	•HITSP Publishes Interoperability Specification	• Industry Tests • HHS Recognizes • Certification
AHIC Successor			• *Stand up the Successor* • *Establish prioritization model*	• *Successor Selects Priorities* • *Initiates standards identification / harmonization*	• *Continues standards identification / harmonization processes . . .*

For More Information…

- Please attend the June 4 AHIC Successor Public Meeting
  - June 4, 2008 (9 am to 12 pm) at the Brooking Institution's Falk Auditorium
  - Please visit the AHIC Successor Home Page at www.ahicsuccessor.org for a link to the webcast (the link will be activated approximately 10 minutes before the meeting)
  - Call-in number: 1-877-228-3100

    Passcode: 869447

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The National HIT Agenda and Accelerating Interoperability

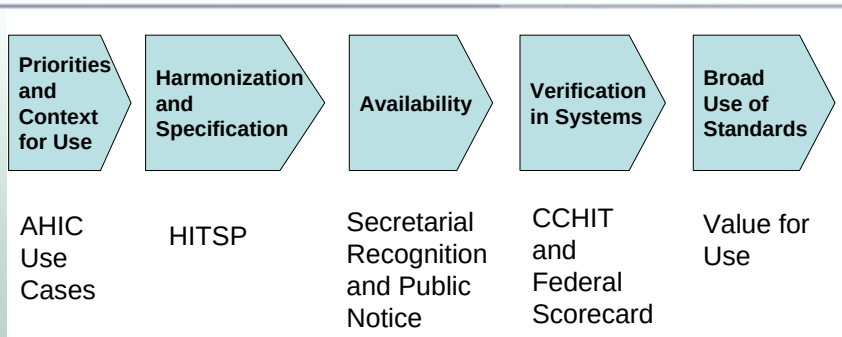
John W. Loonsk
Office of the National Coordinator for Health Information Technology

June 3, 2008

Accelerating Interoperability

- Interoperability - ensuring that health IT systems can easily exchange useful information
  - Reduced implementation / integration costs
  - Increased information exchange
  - Security and confidentiality
- Interoperability is necessary, but not sufficient, for information exchange

The National HIT Agenda Standards Cycle



AHIC Use Cases

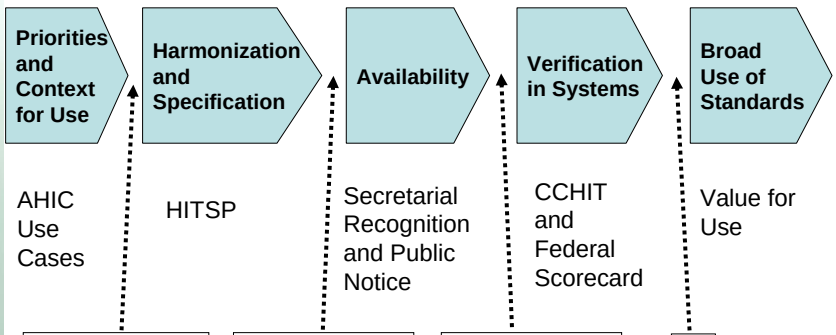
HITSP

Secretarial Recognition and Public Notice

CCHIT and Federal Scorecard

Value for Use

The National HIT Agenda Standards Cycle



AHIC Use Cases

HITSP

Secretarial Recognition and Public Notice

CCHIT and Federal Scorecard

Value for Use

102 "data exchange requests" from 2008 AHIC use cases

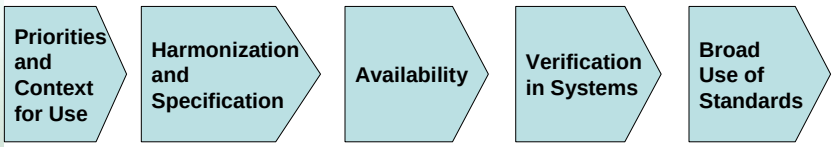
60 "accepted" standards from 2007 AHIC use cases

52 "recognized" standards from 2006 AHIC use cases

?

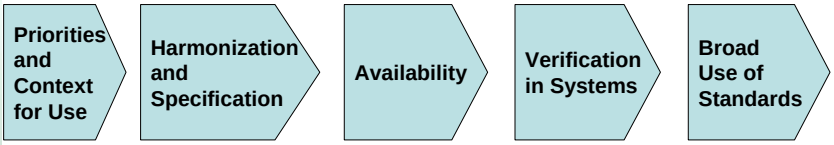
- - - "Work In Process" - - -

Challenges to Standards Use



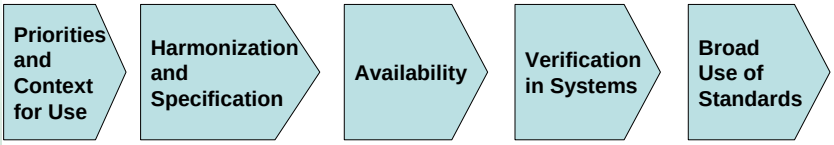
- Challenges to use of standards:
  - Limited incentives for exchanging information
    - When "value" of exchanging is high it costs to not use standards
  - Many incentives for not exchanging information
    - Data "ownership"
    - Integration services profits
    - Existing non standards-based systems
  - Historically – was a problem with the availability of definitive and detailed standards

Challenges for Standards Harmonization



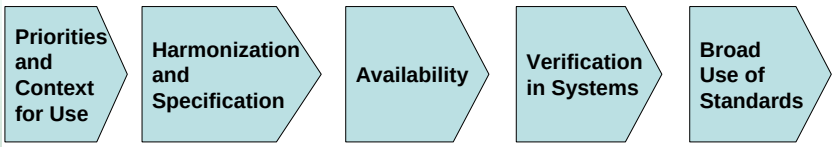
- Availability of standards
  - Agenda and HITSP have made significant progress in making definitive and specific standards available
- Ongoing challenges to standards harmonization
  - In some areas, identifying a single standard, a help for interoperability, is challenged by the variation in installed systems
  - "Tightness" of specifications
    - Testable standards need to be very specific and "tight"
  - Communication of highly technical and complex material

Existing Levers for Standards Use



- Existing levers for increasing value of standards use:
  - Voluntary certification
    - Stark exception and anti-kickback relaxation
    - CMS EHR demo
  - Use in federal systems and contracts (EO)
  - Legislation for administrative standards (HIPAA)

Challenges for Driving Standards Use with Certification



- CCHIT has made significant progress in interoperability
- Challenges for using certification as “driver” of standards use
  - Voluntary
  - Product vendors, the purchasers of certification, are challenged to rapidly implement detailed standards
    - Driven by market needs for products – value of interoperability is mostly perceived to be lower than the costs
    - Product value of societal benefits (e.g. Biosurveillance)?
  - Limited “participants”
    - e.g. for lab result exchange, test EHR alone vs. EHR and labs
  - Needs for technical testing infrastructure

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Office of the National Coordinator for Health Information Technology

American Health Information Community

Standards Update

John D. Halamka
Healthcare Information Technology Standards Panel (HITSP)

June 3, 2008

Interoperability Standards - Background

Round #1 2006 Use Cases	Round #2 2007 Use Cases	Round #3 2008 Use Cases
• IS01 – Electronic Health Record Laboratory Results Reporting • IS02 - Biosuveillance • IS03 – Consumer Empowerment	• IS04 – Emergency Responder Electronic Health Record • IS05 – Consumer Access to Clinical Information • IS06 – Quality • IS07 – Medication Management • Security and Privacy Constructs (deferred from Round 1)	• Consultations and Transfer of Care • Personalized Healthcare • Immunizations and Response Management • Public Health Case Reporting • Remote Monitoring • Patient Provider Secure Messaging

Interoperability Standards – Background

- Round #1
  - January 2008 Secretary recognized interoperability standards for 2006 use cases
- Round #2
  - January 2008 Secretary accepted interoperability standards for Security and Privacy and 2007 use cases
  - Exceptions: Medication Management Use Case and Reliable Document Interchange
- Round #3
  - HITSP is currently harmonizing interoperability standards for 2008 use cases (6)
  - Scheduled for acceptance in January 2009

Interoperability Standards - Today

- Interoperability standards advanced today for acceptance (to be recognized in June 2009) include….
  - IS07 Medication Management
  - T31 Document Reliable Interchange
- Round #1 Interoperability Specifications have been updated with minor updates of a technical nature to reference the Security and Privacy standards
  - IS01 Electronic Health Record Lab Results Reporting Interoperability Specification (V3.0)
  - IS02 Biosurveillance Interoperability Specification (V3.0)
  - It is expected that these specifications will be recognized along with the Security and Privacy standards in January 2009

IS07 – Medication Management Interoperability Specification (v1.0)

- Defines specific standards to facilitate access to necessary medication and allergy information for consumers, clinicians, pharmacists, health insurance agencies, inpatient and ambulatory care, etc.
- Includes four new HITSP constructs
  - T40 Patient Generic Health Plan Eligibility Verification
  - T42 Medication Dispensing Status
  - TP43 Medication Orders
  - TP46 Medication Formulary and Benefits Information
- HITSP worked with CMS to ensure IS07 was consistent with the ePrescribing federal initiative led by CMS including, when applicable, adherence to standards required for ePrescribing under Part D of the Medicare Modernization Act (MMA)

IS07 – Medication Management Interoperability Specification (v1.0) - Working With CMS

- IS07 uses the version of the NCPDP SCRIPT Standard Implementation Guide cited in MMA (currently Version 8.1) in most circumstances and Version 10.1 to include specialized data elements not included in Version 8.1
- To obtain and exchange local patient identifiers for communication between prescriber, dispenser, and payer organizations, IS07 defined a bridge between standards typically used in prescriber settings (HL7) with those typically used in payer and dispenser settings (NCPDP and X12N)
- For exchange of a patient's medication history, IS07 uses standards consistent with MMA to exchange medication history detail (NCPDP SCRIPT) and standards to include medication history in a clinical summary that also includes allergies, problem lists, etc. (HITSP C32 summary document)

T31 Document Reliable Interchange (v1.0)

- Provides a standards-based mechanism for conveying a set of medical documents in a point-to-point network-based communication
  - May involve direct interchange between EHRs, PHRs, Quality Measurement Organizations, Public Health Authorities and other healthcare IT systems in the absence of a document sharing infrastructure such as that enabled by the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework.
  - The content of the communication might be clinical documents, quality documents or public health documents.
- Uses the IHE *Cross-Enterprise Document Reliable Interchange (XDR)* Integration Profile, a companion to the IHE *Cross-Enterprise Document Sharing (XDS)* Integration Profile

Next Steps

- HITSP is asking that the AHIC recommend this work to the HHS Secretary for his acceptance / recognition
  - IS07 Medication Management Interoperability Specification (V1.0)
  - T31 Document Reliable Interchange (V1.0)

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American Health Information Community

Health IT Certification Update from CCHIT

Mark Leavitt
Certification Commission for Healthcare Information Technology

June 3, 2008

Topics

- Status Update
  - Recap of Certification Program Results
  - Status of 2008 Criteria Development
  - Progress in Interoperability
- Looking Ahead
  - Strategic Directions
  - Expansion Roadmap
  - Sustainability of the Certification Initiative

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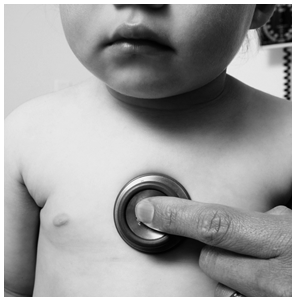
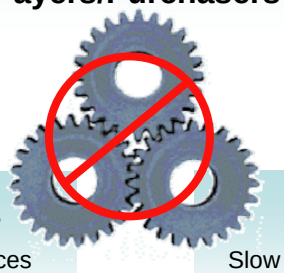
Status Update



The EHR Adoption Deadlock

Will not offer adoption incentives unless EHRs benefits are assured

Payers/Purchasers



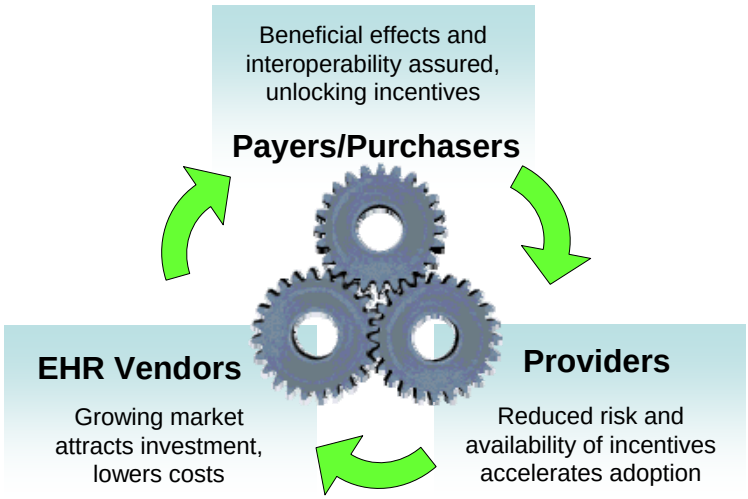
EHR Vendors

Can not lower prices until provider adoption accelerates

Providers

Slow to buy EHRs until costs and risks are lower and/or incentives higher

Goal of Certification: A Positive Feedback Cycle



Acceptance by Providers

Professional society endorsements:

- AAFP
- AAP
- ACP
- ACC
- ACEP
- AMA
- MGMA
- Physician's Foundations

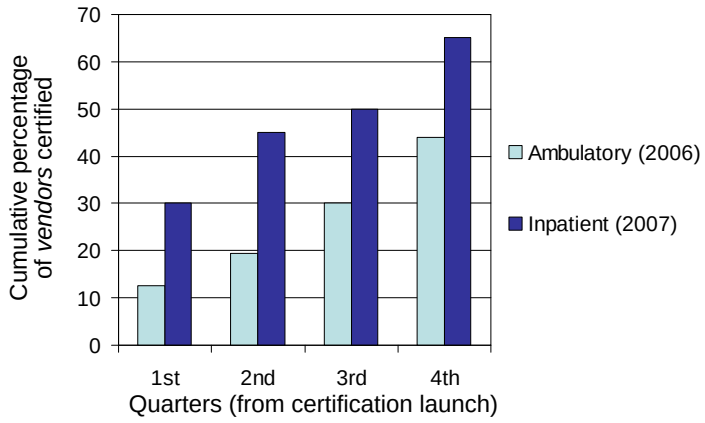
Impact surveys:

- 72% of physicians believe published certification standards have an impact on EHR adoption[1]
- 66% of CIOs are aware of certification; 55% of them plan to require it in their purchase decisions[2]

[1] MGH Institute for Health Policy, George Washington University and RTI, A National Survey of Health Record Keeping among Physicians & Group Practices in the United States, preliminary data report to AHIC, Jan 2008

[2] Survey conducted by HIMSS Analytics, March 2007

Acceptance by Vendors



Over 150 EHR products certified in 2 years
Certified vendors represent more than 75% of the EHR marketplace

Certification is Enabling EHR Adoption Incentives

Public Sector:

- CMS EHR demo project
- Stark/AKA safe harbor for donation of certified EHRs
  - 49 Ambulatory EHR products currently qualified
  - Surveys show strong interest
  - Rollouts announced
- State eHealth initiatives
  - EHR adoption grants linked to CCHIT certification

Private Sector:

- EHR adoption incentives announced by several health plans
  - 9% of payers now offer EHR adoption incentives[1]
- Physician liability insurance
  - Several insurers offer 3-5% premium discount for implementation of certified EHRs[2]

[1] The eValue8 Cornerstone Report, National Business Coalition on Health, October 2007
[2] Data from press releases by insurers; more extensive survey conducted by PIAA is pending

Status of 2008 Criteria Development

Updated Domains:

- Ambulatory EHR 08:
  - Proposed Final Criteria published April 17
  - Final Criteria published May 20
  - Certification applications open July 1
  - Optional additional certifications available:
    - Child Health
    - Cardiovascular Medicine
- Inpatient EHR 08
  - Proposed Final Criteria published May 20
  - Final Criteria will be published June 20
  - Certification applications open August 1

Status of 2008 Criteria Development

New Domains:

- Emergency Department EHR 08
  - Proposed Final Criteria published May 20
  - Final Criteria will be published June 20
  - Certification applications open August 1
- Health Information Exchange 08
  - Alpha testing complete
  - Pilot Testing under way this month
  - Final Criteria will be published in August
  - Certification applications open October 1

Progress in Interoperability

- 2006
  - Receiving lab results in Ambulatory EHRs (basic)
- 2007
  - Stronger compliance testing of lab results in Ambulatory EHRs
  - ePrescribing in Ambulatory EHRs
- 2008
  - Stronger compliance testing of lab results in Ambulatory EHRs
  - Additional ePrescribing functions in Ambulatory EHRs
  - Sending and receiving clinical summaries (CCD) in Ambulatory and Inpatient EHRs
  - Transmitting lab results and clinical summaries via networks/health information exchanges

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Looking Ahead

Strategic Directions

- Expand certification to new healthcare domains
- Guided by AHIC priorities and HITSP standards readiness, drive standards-based interoperability into all certified health IT systems
- Enhance technical robustness and automation of certification inspection and testing
- Enhance outreach and communications

Expansion Roadmap

Expansion Area	2008	2009	2010
Populations			
Behavioral Healthcare	Begin Development	Launch Certification	
Care Settings			
PHRs	Begin Development	Launch Certification	
Long Term Care	Begin research	Begin Development	Launch Certification
Professional Specialties			
Other Specialties	Predevelopment Research	Begin Development	Launch Certification

Financial Sustainability

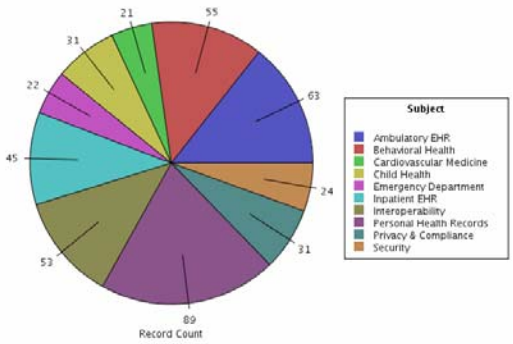
Transition from contract funding to self-sustainability is tracking to our plan:

Year	2006	2007	2008	2009	2010
% of revenues from 3-yr HHS contract and 1-yr optional extension	72%	56%	52%*	20%*	0%*
% of revenues from certification activities and other funding sources	28%	44%	48%*	80%*	100%*

*Projected

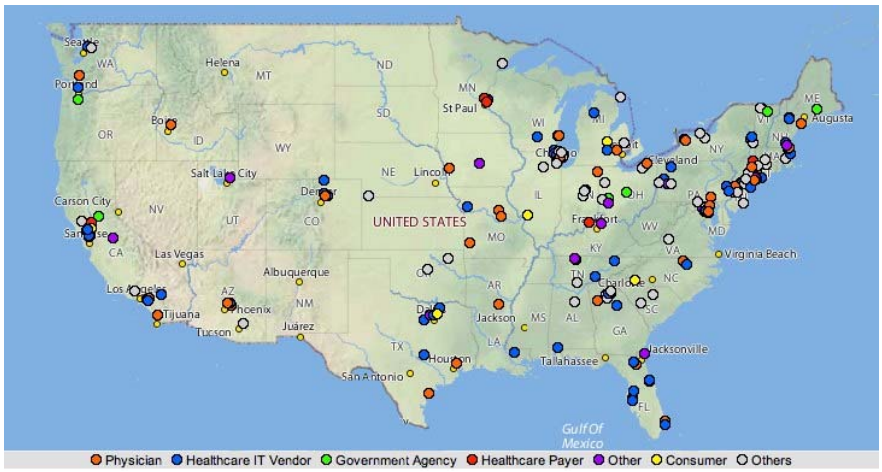
Volunteer Interest for 2009

- 280 individuals submitted over 500 applications for 150 positions
- 2 volunteers applied for every 1 position (average)
- Newest groups: Behavioral Health = 4 to 1 PHR = 6 to 1



Strong volunteer interest is best indicator of continuing vitality of CCHIT's efforts

Geographic and Stakeholder Diversity of Volunteers



Summing Up

- Certification showing positive acceptance and impact
- Criteria and certification programs for 2008 are ready
- Significant progress in driving standards-based interoperability into health IT products has been made; will accelerate in years to come
- Certification is on track to sustainability, and support from the stakeholder community remains strong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Health Information Technology

Thank You! Q & A

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Office of the National Coordinator for Health Information Technology

American Health Information Community

AHIC 2009 Priorities for Use Case Extensions/Gaps

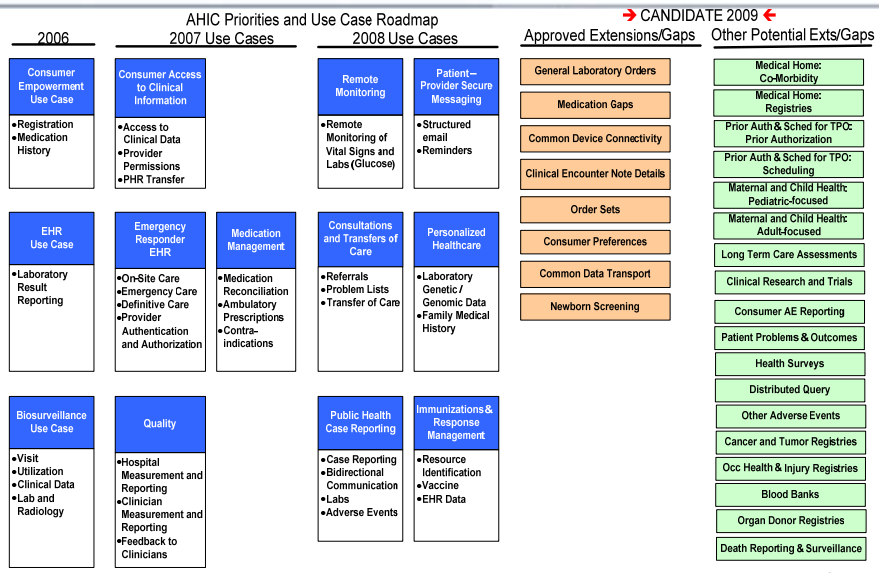
John W. Loonsk
Office of the National Coordinator for Health Information Technology

June 3, 2008

2009 AHIC Priorities

- At April AHIC meeting
  - Discussion on adding new use cases vs. doing extensions / gaps
  - 7 extensions/gaps were approved (tally = 5 or greater) for immediate development
- Secretary Leavitt has identified a full Newborn Screening use case as an important priority for HHS
- Have distributed a new list of extensions / gaps for your prioritization that includes some needs from the “old” 2009 use case list

AHIC Priorities and Use Case Roadmap (Updated)



Results of AHIC Member Feedback

Medical Home: Co-Morbidity	10
Medical Home: Registries	10
Maternal & Child Health: Pediatric-focused	9
Prior-Authorization and Scheduling in Support of Treatment, Payment, and Healthcare Operations: Scheduling	9
Maternal & Child Health: Adult-focused	8
Patient/Consumer Adverse Event Reporting	8
Prior-Authorization and Scheduling in Support of Treatment, Payment, and Healthcare Operations: Authorization Info	6
Long-term Care & Assessment	6
Distributed Query	5
Clinical Research-Availability of Clinical Trials to EHRs	5
Patient Reported Problems and Outcomes	5
Other Adverse Events	5
Cancer and Tumor Registries	4
Health Surveys	2
Death Reporting and Surveillance	2
Occupational Health and Injury Registries	1
Blood Banks	1
Organ Donor Registries	1

Medical Home: Co-Morbidity 10

- Convinced that use case is not needed but extensions are on this topic
- Supports chronic care and complex case management.
- Will improve quality of care; impacts large population
- Supports better care management
- Multiple chronic illness is major cost in health care system
- Primary care coordination is essential to quality health care delivery by health plan providers especially for patients with co-morbid conditions.
- Especially useful for people who use multiple providers for multiple conditions, chronic care and complex care. (Consider evaluation of the NCVHS population work group activities related to the concept of 'medical home'/care coordination.)

Medical Home: Registries 10

- Convinced that use case is not needed but extensions are on this topic
- Supports chronic care and complex case management.
- Will improve quality of care; impacts large population
- Supports better care management
- Multiple illness is major cost in health care
- Primary care coordination is essential to quality health care delivery by health plan providers especially for patients with co-morbid conditions.
- Especially useful for people who use multiple providers for multiple conditions, chronic care and complex care. (Consider evaluation of the NCVHS population work group activities related to the concept of 'medical home'/care coordination.)

Maternal & Child Health: Pediatric-focused 9

- Important health and social issue.
- Supports personalized health care and population health initiatives.
- Logical extension to both Consultation and Transfers of Care and Immunizations and Response Management use cases as well as the new Newborn Screening use case; added benefit is impact to Public Health Case Reporting use case
- Would improve our and States abilities to coordinate assessment (and placement for "4") for the subpopulations of Medicaid
- Makes sense to get kids started with EHRs as they will be next generation of users
- This would provide important clinical decision support functions to physicians and patients.
- Structured approach today makes systems possible

Prior-Authorization and Scheduling in Support of Treatment, Payment, and Healthcare Operations: Scheduling 9

- Very valuable to ambulatory based care.
- Supports patients' ability to management their health care needs. Can assist practice or clinic managers with resource utilization and optimization.
- Large benefit to both clinicians and consumers
- This would remove significant barriers in terms of patient convenience and provider administrative burden
- This would increase the functionality of PHRs available to Federal enrollees.
- Already in digital environment
- Facilitates service coordination and empowers patients in their own self health management.

Maternal & Child Health: Adult-focused 8

- Important health and social issue.
- Supports personalized health care and population health initiatives.
- Logical extension to both Consultation and Transfers of Care and Immunizations and Response Management use cases as well as the new Newborn Screening use case; added benefit is impact to Public Health Case Reporting use case
- Improves ability to coordinate assessment information among various care settings.
- Necessary for young adults – should aid in establishing usefulness for parents with young children in getting them to use EHRs
- This could result in increased clinical decision support tools for physicians and patients.
- Structured approach today makes systems possible

Patient/Consumer Adverse Event Reporting 8

- Supports patient empowerment, post-market surveillance for safety and quality
- Will build consumer confidence; step toward patient centric care
- This would allow proactive reporting rather than waiting for the patient to visit the provider
- Might help to get modern day communications into health care.
- This is essential for post-marketing surveillance of medications and medical devices
- Facilitates post-market surveillance for safety and quality, and improves PHY and EHR's data communication.

Prior-Authorization and Scheduling in Support of Treatment, Payment, and Healthcare Operations: Authorization Info 6

- Very valuable to ambulatory based care.
- Large impact; easily built on current foundation; will simplify administration

- This would remove significant barriers in terms of patient convenience and provider administrative burden
- These areas of health plan and provider interaction are in need of streamlining through automation.

Long-term Care & Assessment 6

- Extends existing use case to additional care venue; meets demands of aging population
- Would improve our and States abilities to coordinate assessment (and placement for "4") for the subpopulations of Medicaid
- Long term care (chronic illness) is key to cost in health care
- Supports the development of disability assessment and functional status assessments necessary to care of patient transitioning from acute, rehab, outpatient and LT care

Distributed Query 5

- Large impact on surveillance, control of outbreaks, homeland security
- This may not be as difficult as it seems and facilitates rapid collection of data for bio-surveillance.

Clinical Research-Availability of Clinical Trials to EHRs 5

- Supports standardized, consistent patient education regarding treatment options. Fosters patient empowerment.
- Of benefit to both consumers and clinical research
- This could result in robust real-time clinical decision support tools for physicians and patients.
- Very useful for both patient education of opportunity and recruitment for clinical trails. Consider expanding the 'prompt physicians' prompt to include other providers and patients. (At one time, wasn't there an activity from NIH/NCI/Dr. Deering to target a patient's ability to subscribe to a service to prompt notification of clinical trials?)

Patient Reported Problems and Outcomes 5

- Supports quality, population health, and potentially enables the provider to have a more complete picture of a patient's health concerns.
- This would allow proactive reporting rather than waiting for the patient to visit the provider
- This is essential in reporting and preventing adverse events.
- Self reporting data often reflect more closely to the conditions when events were occurring

Other Adverse Events 5

- Supports patient empowerment, post-market surveillance for safety and quality, and public health monitoring activities.
- This is essential for post-marketing surveillance.
- Improve timeliness of notification.

Cancer and Tumor Registries 4

- Complements clinical research, population health activities, disease management.
- Mostly digital
- Improve timeliness of notification.

Health Surveys 2

- Simple use of modern technology to gather data to help patients get the best care and identify problems

Death Reporting and Surveillance 2

- Makes sense to be able to timely report deaths and tabulate data

Occupational Health and Injury Registries 1

Blood Banks 1

- Simple use of IT to track blood data

Organ Donor Registries 1

- Simple use of IT to help track transplant information

Department of Health & Human Services
Office of the National Coordinator for Health Information Technology

American Health Information Community

Personalized Health Care Workgroup Recommendations

Douglas E. Henley
American Academy of Family Physicians

Janet A. Warrington
Consultant

June 3, 2008

Personalized Health Care (PHC) Workgroup Member List

- **Co-Chairs:**
  - John Glaser — Partners HealthCare
  - Douglas Henley — American Academy of Family Physicians
- **Staff Co-Chair:**
  - Gregory Downing — Office of the Secretary, HHS
- **Members:**
  - Carolyn Clancy — Agency for Healthcare Research and Quality
  - Beryl Crossley — American Clinical Laboratory Association, Quest
  - Paul Cusenza — Entrepreneur and Consultant
  - Andrea Ferreira-Gonzalez — Virginia Commonwealth University
  - Becky Fisher — Patient Advocate
  - Felix Frueh — Food and Drug Administration
  - Emory Fry — Department of Defense
  - Alan Guttmacher — National Institutes of Health/NHGRI
  - Kathy Hudson — Genetics and Public Policy Center
  - Betsy Humphreys — National Institutes of Health/NLM
  - Charles Kennedy — WellPoint
  - Joel Kupersmith — Department of Veterans Affairs
  - Stephen Matteson — Pfizer
  - Deven McGraw — National Partnership for Women and Families
  - Amy McGuire — Baylor College of Medicine
  - Mark Rothstein — University of Louisville
  - Steve Teutsch — Merck
  - Janet Warrington — Consultant
  - Andrew Wiesenthal — Permanente Federation
  - Dennis Williams — Health Resources and Services Administration
  - Marc Williams — Intermountain Healthcare

PHC Workgroup Senior Advisors

- **Senior Advisors:**
  - Mary Beth Bigley — Office of the U.S. Surgeon General
  - Greg Feero — National Institutes of Health/NHGRI
  - Joseph Kelly — Centers for Medicare & Medicaid Services
  - Muin Khoury — Centers for Disease Control and Prevention
  - Katherine Kolor — Centers for Disease Control and Prevention
  - Michele Lloyd-Puryear — Health Resources and Services Administration
  - Elizabeth Mansfield — Food and Drug Administration
  - Clement McDonald — National Institutes of Health/NLM
  - Armando Oliva — Food and Drug Administration
  - Dina Paltoo — National Institutes of Health/NHLBI
  - Jonathan Perlin — HCA, Inc.
  - Ronald Przygodzki — Department of Veterans Affairs
  - Gurvaneet Randhawa — Agency for Healthcare Research and Quality
  - Lisa Rovin — Food and Drug Administration
  - Maren Scheuner — RAND Corporation
  - Jean Slutsky — Agency for Healthcare Research and Quality
  - Reed Tuckson — UnitedHealth Group; SACGHS
  - Mollie Ullman-Cullere — Harvard Partners Center for Genetics and Genomics
  - Grant Wood — Intermountain Healthcare

PHC Workgroup Overview

Broad Charge:

Make recommendations to the Community for a process to foster a broad, community-based approach to establish a common pathway based on common data standards to facilitate the incorporation of interoperable, clinically useful genetic/genomic information and analytical tools into electronic health records to support clinical decision-making for the clinician and consumer.

Specific Charge:

Make recommendations to the Community to consider means to establish standards for reporting and incorporation of common medical genetic/genomic tests and family health history data into electronic health records, and provide incentives for adoption across the country including federal government agencies.

PHC Vision and Priorities

- Personalized Health Care is a consumer-centric system in which clinicians customize diagnostic, treatment, and management plans
- Four perspectives were identified as important to the vision
  - Consumer
  - Clinician
  - Researcher
  - Health Plan/Payer
- Four priority areas across each perspective
  - Genetic/Genomic Tests
  - Family Health History
  - Confidentiality, Privacy, and Security
  - Clinical Decision Support

Pharmacogenomics (PGx) Subgroup Member List

- **Co-Chairs:**
  - Dina Paltoo* — NIH/National Heart, Lung, and Blood Institute
  - Janet Warrington* — Consultant
- **Members:**
  - Richard Anderson — NIH/National Institute of General Medical Sciences
  - Marcie Bough — American Pharmacists Association
  - Michael Caldwell — Marshfield Clinic
  - Jason DuBois — American Clinical Laboratory Association
  - Greg Feero* — NIH/National Human Genome Research Institute
  - Lynne Gilbertson — National Council for Prescription Drug Programs
  - Joyce Hernandez — Merck
  - Anne Johnston — Gold Standard, Inc.
  - Rebecca Kush — Clinical Data Interchange Standards Consortium
  - Frederick Lee — McKesson
  - Roberta Madej — Roche Molecular Systems
  - Catherine McCarty — Marshfield Clinic
  - Andrew Mellin — McKesson
  - David Mongillo — American Clinical Laboratory Association
  - Kay Morgan — Gold Standard, Inc.
  - Ronald Przygodzki* — Department of Veterans Affairs

*Member / Senior Advisor of the Personalized Health Care Workgroup

PGx Subgroup Member List (cont.)

- **Members:**
  - Gurvaneet Randhawa* — Agency for Healthcare Research and Quality
  - Patricia Rowell — Department of Veterans Affairs
  - Allen Rudman — Food and Drug Administration
  - Pauline Sieverding — Department of Veterans Affairs
  - Ansalan Stewart — Assistant Secretary for Planning and Evaluation
  - Annette Taylor — Kimball Genetics
  - Mollie Ullman-Cullere* — Harvard Partners Center for Genetics and Genomics
  - Michele Vilaret — National Association of Chain Drug Stores
  - Phillip Vuchetich — Alegent Health
  - Ken Whittemore — SureScripts
  - Chelle Woolley — Consultant
- **Staff:**
  - Gregory Downing — Office of the Secretary, HHS
  - Kristin Brinner — Office of the Secretary, HHS
  - Scott Boyle — Office of the Secretary, HHS
  - Lauren Kim — BearingPoint

*Member / Senior Advisor of the Personalized Health Care Workgroup

Background

- Pharmacogenomics is defined as the study of variations of DNA and RNA (genes and gene products) characteristics as related to drug response
  - Pharmacogenetics is a subset of pharmacogenomics and is limited to variations in DNA
- PGx has the potential to inform therapeutic choices, clarify dosing decisions, reduce adverse drug reactions, and optimize prescribing patterns of providers
- PGx is novel to health care providers and the information generated from the laboratory is very complex
- Examples of clinical scenarios where PGx testing may apply include:
  - Anticoagulation therapy (warfarin)
  - Carbamazepine-containing drugs

Background (cont.)

- Integration into routine clinical practice has been slow due to:
  - Lack of an evidence-base and information on clinical utility
  - Lack of clinical guidelines for the use and interpretation of pharmacogenomic tests in pharmaceutical selection and treatment decisions
  - Impediments to reimbursement for the performance of laboratory tests
  - Paucity of clinical practice experience with pharmacogenomic test applications
- Increased or improved EHR functionality may help motivate clinician adoption of electronic tools and pharmacogenomics

Fostering EHR Data Standards to Enable Clinical Research and Development Activities

Recommendation 1.0: HHS agencies should maintain existing relationships with appropriate standards development organizations (SDOs) and industry stakeholders to expand the standards development process for documenting pharmacogenomic data and for submitting to other databases.

> **Recommendation 1.0.1:** HHS agencies and the National Institute of Standards and Technology (NIST) should work together to clarify and determine the role that each will play in developing standards for pharmacogenomic data.

☐ **Accept** ☐ **Table** ☐ **Reject**

Fostering EHR Data Standards to Enable Clinical Research and Development Activities (cont.)

Recommendation 1.1: FDA, National Institutes of Health (NIH), and other federal agencies involved in clinical research should convene a workgroup and develop a document or checklist that clarifies best practices for use of informed consent between patients and caregivers and for data use by physicians, pharmacists, regulators, researchers, and other relevant stakeholders when pharmacogenomics data is submitted to research databases. Issues to consider include: national privacy standards; de-identification of data; appropriate use of data; and educational information to provide to research participants.

☐ **Accept** ☐ **Table** ☐ **Reject**

Fostering EHR Data Standards to Enable Clinical Research and Development Activities (cont.)

Recommendation 1.2: Coordinated by the Agency for Healthcare Research and Quality (AHRQ), HHS agencies, including FDA and NIH, should identify a core set of data elements relevant to the outcomes of clinical interventions driven by pharmacogenomic tests that need to be captured in EHRs. HHS should facilitate development of standards for coding these outcomes data and standards that enable exchange of pharmacogenomic test results and/or interpretations from different EHR platforms and other databases that collect relevant outcomes data, while ensuring the confidentiality and privacy of a patient's information. HHS should facilitate standardization of methodologies to analyze and report outcomes of pharmacogenomic tests.

☐ **Accept** ☐ **Table** ☐ **Reject**

Fostering EHR Data Standards to Enable Clinical Research and Development Activities (cont.)

Recommendation 1.3: AHRQ, NIH, and federal health care providers should identify opportunities for and encourage pilot projects to demonstrate the use of EHRs for supporting clinical research and integrating pharmacogenomic data into clinical research databases utilizing existing standards and terminology.

☐ **Accept** ☐ **Table** ☐ **Reject**

Fostering EHR Data Standards to Enable Clinical Research and Development Activities (cont.)

Recommendation 1.4: A multi-stakeholder workgroup, including clinicians, health IT specialists, industry, laboratories developing or performing pharmacogenomic tests, medical device/product reviewers, pharmacists, and researchers, should be formed to develop a core minimum data set (potentially including gene names, gene mutations, coded interpretations, and associated medications) and common data definitions available for inclusion of pharmacogenomics data with demonstrated clinical validity and utility in an EHR.

☐ **Accept** ☐ **Table** ☐ **Reject**

Fostering EHR Data Standards to Enable Clinical Research and Development Activities (cont.)

Recommendation 1.5: The unidirectional information-flow from EHRs to clinical research applications (such as case report forms) should be prioritized for Use Case Development.

☐ **Accept** ☐ **Table** ☐ **Reject**

Clinical Decision Support in Health Care Delivery

Recommendation 2.0: When the public-private CDS entity is developing strategies to incorporate accepted CDS technologies into health care information technology and clinical processes, and describing high level, standard workflows and types of CDS interventions that are applicable to health professionals' workflows, the electronic exchange of clinically useful pharmacogenomic and other relevant health information among the patient, pharmacist, and prescribing clinician should be considered.

☐ **Accept** ☐ **Table** ☐ **Reject**

Clinical Decision Support in Health Care Delivery (cont.)

Recommendation 2.1: When developing a minimum data set of personal attributes that contribute to individualized care, the public-private CDS entity should include pharmacogenomic test information and/or interpretations as part of that minimum data set.

☐ **Accept** ☐ **Table** ☐ **Reject**

Clinical Decision Support in Health Care Delivery (cont.)

Recommendation 2.2: AHRQ and NIH should continue to work with appropriate agencies and organizations, including clinical laboratories, to evaluate how pharmacogenomics-related CDS tools affect clinicians' and patients' decision-making, and to ensure that developed tools will be utilized by end-users. Clinician expertise and complicating factors such as comorbidities and polypharmacy need to be examined in combination with the CDS tools.

☐ **Accept** ☐ **Table** ☐ **Reject**

Clinical Decision Support in Health Care Delivery (cont.)

Recommendation 2.3: The public-private CDS entity and CDS Collaboratory should include standards for reporting, annotating, tracking, and updating versions of pharmacogenomic and related algorithms. Algorithms should be stored in a CDS repository and should be continually updated as new variants and/or pharmacogenomic data are developed.

☐ **Accept** ☐ **Table** ☐ **Reject**

Integrating Pharmacogenomics into Medication Prescribing Practices

Recommendation 3.0: HHS should work with stakeholders, including professional associations representing clinicians, clinical laboratories, pharmacists, and others, to develop a white paper on the opportunities and challenges associated with dispensing pharmaceutical drugs based on pharmacogenomic test-derived interpretations in inpatient, ambulatory, and mail-order services. Issues to consider may include: incorporation into workflow, identification of the party responsible for utilizing the dosing algorithm (which incorporates pharmacogenomic data with other clinical data), identification of contraindications, and ensuring that testing precedes dispensing, where appropriate.

☐ **Accept** ☐ **Table** ☐ **Reject**

Integrating Pharmacogenomics into Medication Prescribing Practices (cont.)

Recommendation 3.1: The information-flows between the clinical laboratory, patient, pharmacist, and prescribing clinician, including pharmacogenomic-based dosing interpretation of clinically validated test/drug combinations, within e-prescribing technology should be prioritized for Use Case Development.

☐ **Accept** ☐ **Table** ☐ **Reject**

Integrating Pharmacogenomics into Medication Prescribing Practices (cont.)

Recommendation 3.2: AHRQ, CDS Collaboratory, and FDA should convene a meeting with various stakeholders, including associations representing clinicians, patients, and pharmacists; clinical laboratories that develop and perform pharmacogenomic tests; commercial drug database industry; EHR vendors; e-prescribing vendors; and other organizations to determine how information from FDA label changes may be integrated into electronic prescribing or CDS tools for point-of-care decision-making.

☐ **Accept** ☐ **Table** ☐ **Reject**

Integrating Pharmacogenomics into Medication Prescribing Practices (cont.)

Recommendation 3.3: National Library of Medicine (NLM) should lead an effort to complete and vet an ongoing activity to integrate structured genetic information, including pharmacogenomic test results and interpretations, into an EHR/PHR. This effort should include necessary normalization and translation of clinical standards into those compatible with the research setting.

☐ **Accept** ☐ **Table** ☐ **Reject**

June 3, 2008

The Honorable Michael O. Leavitt
Chairman
American Health Information Community
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Chairman:

The American Health Information Community (AHIC) has given the following broad charge to the Personalized Health Care Workgroup:

> **Broad Charge for the Workgroup:** Make recommendations to the American Health Information Community for a process to foster a broad, community-based approach to establish a common pathway based on common data standards to facilitate the incorporation of interoperable, clinically useful genetic/genomic information and analytical tools into electronic health records to support clinical decision-making for the clinician and consumer.

The Workgroup's deliberations have highlighted a number of key issues regarding the broad charge, including the following:

1. Genetic/Genomic Tests
2. Family Health History
3. Clinical Decision Support
4. Confidentiality, Privacy, and Security

This letter provides both context and recommendations for how the issues of pharmacogenomic laboratory test information and the interface of electronic health record (EHR) systems with clinical research can be addressed in the next twelve months.

BACKGROUND

Personalized Health Care (PHC) represents a *systems* approach to support patient-centric health care by integrating genetic/genomic test information and health information technology (IT). Pharmacogenomics is defined as the study of variations of DNA and RNA [genes and gene products] characteristics as related to drug response; pharmacogenetics is a subset of pharmacogenomics and is limited to variations in DNA.[1, 2] Pharmacogenomics has the potential to inform therapeutic choices, clarify dosing decisions, reduce adverse drug reactions, and optimize prescribing patterns of providers.

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[1] EMEA, November 2007, ICH Topic E15, *Note for guidance on definitions for genomic biomarkers, pharmacogenomics, pharmacogenetics, genomic data and sample coding categories, EMEA/CHMP/ICH/437986/2006.*
[2] FDA Guidance for Industry, E15 *definitions for genomic biomarkers, pharmacogenomics, pharmacogenetics, genomic data and sample coding categories* http://www.fda.gov/cder/Guidance/8083fnl.pdf

Despite the promise of pharmacogenomics, its integration into routine clinical practice has been slow due to several issues, including: lack of an evidence-base and information on clinical utility; lack of clinical guidelines for the use and interpretation of pharmacogenomic tests in pharmaceutical selection and treatment decisions; impediments to reimbursement for the performance of laboratory tests; and a paucity of clinical practice experience with pharmacogenomic test applications. These may be overcome through the interface of pharmacogenomics with clinical decision support (CDS) tools and clinical research for incorporation into clinical care. The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) recently released a report on pharmacogenomics, *Realizing the Promise of Pharmacogenomics: Opportunities and Challenges*[3], which identifies three recommendations relating to health information technology: studying how clinically validated pharmacogenomic test results are being incorporated into EHRs; ensuring infrastructure is in place to support pharmacogenomics data in EHRs for CDS tools; and exploring development of pilot studies that examine the impact of CDS tools for pharmacogenomic technologies at the point-of-care.

Because of the complexity of pharmacogenomic data relative to other types of laboratory data, structuring pharmacogenomic information in the EHR and providing filtered interpretations with CDS tools are likely necessary for its optimal use in informing drug selection and dosage at the point-of-care by clinicians. This input at the point-of-care may be built on already existing electronic prescribing infrastructure. Additionally, overcoming some of the barriers for incorporating pharmacogenomics into clinical practice may enhance clinical research on pharmacogenomics and its potential to improve patient health. This research may be leveraged by utilizing EHRs to match potential research participants with clinical study requirements, such as being naïve-to-therapy where pharmacogenomic data may inform dosing or alter therapeutic choice, or to provide clinically meaningful outcomes of pharmacogenomic testing.

In summary, it is recognized that the adoption of EHRs and pharmacogenomics in health care practices are at an early stage, but their integration may achieve meaningful clinical improvements and benefit from implementation of a standard format for collection and exchange of pharmacogenomics information prior to widespread deployment. Increased or improved EHR functionality may help motivate clinician adoption of electronic tools and pharmacogenomics.

If accepted by the AHIC, the recommendations from the PHC Workgroup should be considered for adoption by the Department of Health and Human Services (HHS) as HHS policy regarding current and future federal activities as they relate to the Workgroup's charge.

RECOMMENDATIONS

I. Fostering EHR Data Standards to Enable Clinical Research and Development Activities

Currently, EHRs may be used for matching potential research participants with clinical study requirements, such as naïve-to-therapy where pharmacogenomic data may inform dosing or alter therapeutic choice. A recent development in health information technology, Personally Controlled Health Records (PCHRs), may provide another route for electronic matching of

[3] http://www4.od.nih.gov/oba/sacghs/reports/SACGHS_Pgx_report.pdf

eligible participants with clinical studies.[4] In the current system, upon enrolling in the study, pharmacogenomic testing is performed and analyzed as relevant to the purpose of the study. However, in the future health system, the EHR or PCHR may already contain pharmacogenomic information, as well as other genomic and phenotypic data. With appropriate permission, oversight, and authorized access to information, approved entities (such as clinical researchers) could receive the genomic data from an EHR, clinical study case report forms (CRFs), or other databases linking genotype and phenotype for clinical studies. This access may require affirmative patient consent and must conform to appropriate patient consent, security, and privacy safeguards, including the Genetic Information Nondiscrimination Act,[5] the Common Rule (45 CFR 46), Americans with Disabilities Act (Public Law 101-336) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA; Public Law 104-191), FDA rules for Protection of Human Subjects (21 CFR 50), and any applicable state laws.[6] Several other Federal Advisory Committees are considering issues related to oversight of genetic testing,[7] identification of evidentiary gaps,[3] and inclusion of data in EHRs.[8] This future system would provide data for safety assessments, clinical outcomes analysis,[9] best-practice guidelines development, and identification of potential genetic causes for adverse events. Although this system may take years to develop completely, steps can be taken now to enable this future.

Current efforts are underway to address the need for common terminology, data fields, and formats for exchange of pharmacogenomic data, for example from clinical research to the Food and Drug Administration (FDA) through a voluntary data submission program.[10-11] The Clinical Data Interchange Standards Consortium (CDISC), FDA, and National Cancer Institute (NCI) are working together through Health Level Seven (HL7) to develop standards for exchanging data based on the HL7 Reference Information Model to enable the clinical care standards of HL7 to have semantic interoperability with those standards used in research. Additionally, recent work[12] has been done to leverage and extend existing clinical standards (HL7 version 2, Logical Observation Identifiers Names and Codes (LOINC), and Systematized Nomenclature of Medicine (SNOMED)) to support genetics data. The use of LOINC and SNOMED standards should provide linkage of genetics data to other clinical data (e.g., phenotype), as well as speed development of CDS. Standards for the exchange of pharmacogenomic data and submission of such data to FDA are becoming quite mature and available through the collaborative efforts of the HL7 Clinical Genomics Special Interest Group.

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[4] Mandel, K.D. et al. "Tectonic Shifts in the Health Information Economy." *N Engl J Med*, **2008**, *358*, 1732-1737.
[5] H.R. 493 Genetic Information Nondiscrimination Act of 2008: To prohibit discrimination on the basis of genetic information with respect to health insurance and employment, passed by Congress, was recently signed by the President.
[6] These have been enacted to protect the rights of individuals with regard to the access and use of sensitive personal information and to reform group health insurance, respectively. Regulations such as the Privacy Rule and the Security Rule have been promulgated pursuant to HIPAA to address issues regarding shared health information.
[7] http://www4.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf
[8] http://www.hhs.gov/healthit/ahic/
[9] http://effectivehealthcare.ahrq.gov/healthInfo.cfm?infotype=nr&ProcessID=63
[10] http://www.fda.gov/cder/mapp/4180.3.pdf
[11] http://www.fda.gov/cder/genomics/VGDS.htm
[12] Ullman-Cullere, M.; Babb, L.; Heras, Y.; Joshi, V.; McDonald, C.; and Huff, S. "Structured genetic data in the medical record by usage of HL7v2, LOINC, SNOMED, RxNORM and Bioinformatic Standards" *submitted*.

To enable the envisioned scenario and build on current examples, standard terminology, standard metrics, and structured information for outcomes analysis and research are needed to allow data exchange, interoperability, and integration of pharmacogenomic tests into clinical decision-making. Current approaches to Current Procedural Terminology (CPT) codes do not provide sufficient specificity to be utilized in evidence development and health outcomes data analysis. The following areas may also require attention: gene expression data from the various platforms and systems; clinical research information (clinical study CRFs); safety assessment information; and adverse event information.

Given the information described above, the PHC Workgroup makes the following recommendations:

> **Recommendation 1.0:** HHS agencies should maintain existing relationships with appropriate standards development organizations (SDOs) and industry stakeholders to expand the standards development process for documenting pharmacogenomic data and for submitting to other databases.
>
> > **Recommendation 1.0.1:** HHS agencies and the National Institute of Standards and Technology (NIST) should work together to clarify and determine the role that each will play in developing standards for pharmacogenomic data.
>
> **Recommendation 1.1:** FDA, National Institutes of Health (NIH), and other federal agencies involved in clinical research should convene a workgroup and develop a document or checklist that clarifies best practices for use of informed consent between patients and caregivers and for data use by physicians, pharmacists, regulators, researchers, and other relevant stakeholders when pharmacogenomics data is submitted to research databases. Issues to consider include: national privacy standards; de-identification of data; appropriate use of data; and educational information to provide to research participants.

The most important function for EHRs and electronic health information exchange is to facilitate communication between the laboratory, clinician, and patient to support patient care. In order for the clinical implications to be appropriately integrated into clinical workflows, leveragable by CDS, and supplemented with clinical guidelines, health care informatics standards need to be defined to support the transmission of genetic data in highly structured form into EHRs and personal health records (PHRs). While patient care is the principal focus, data in EHRs may serve an important function through supporting clinical research in the unidirectional flow of clinical care information from the EHR into CRFs, data registries, or other research records. Unidirectional flow of information from EHRs into research applications is important, as clinical research data is not appropriate for populating EHRs or PHRs for use in clinical practice. An integration profile called Retrieve Form for Data Capture (RFD), developed through Integrating the Healthcare Enterprise (IHE), enables an EHR to support many reporting needs, such as extract and populate a CRF for research, exchange laboratory and X-ray data, provide biosurveillance and safety reporting, and register clinical trials.

Research discoveries enhanced by consented data from EHRs may result in identification of new pharmacogenomic associations and increased clinical utility and validity of existing genetic tests. For example, the NIH National Cancer Institute-supported Cancer Central Clinical Database

collects clinical study data using standard CRFs based on common data elements. The NCI's Center for Cancer Research is using EHR information linked to laboratory data that is incorporated into the CRFs in the Cancer Central Clinical Database. Other Cancer Central Clinical Database adopters also submit laboratory data that is loaded into the appropriate study in the Cancer Central Clinical Database. The utility of these information exchanges is that data is captured once, thereby improving efficiency and accuracy. In addition to CRFs, the cancer Adverse Event Reporting System monitors laboratory reports to identify any adverse events and aids in the rapid reporting of critical events that may require an adjustment of treatment. Systems such as this may be utilized to enhance pharmacogenomic research and patient health.

Given the information described above, the PHC Workgroup makes the following recommendations:

> **Recommendation 1.2:** Coordinated by the Agency for Healthcare Research and Quality (AHRQ), HHS agencies, including FDA and NIH, should identify a core set of data elements relevant to the outcomes of clinical interventions driven by pharmacogenomic tests that need to be captured in EHRs. HHS should facilitate development of standards for coding these outcomes data and standards that enable exchange of pharmacogenomic test results and/or interpretations from different EHR platforms and other databases that collect relevant outcomes data, while ensuring the confidentiality and privacy of a patient's information. HHS should facilitate standardization of methodologies to analyze and report outcomes of pharmacogenomic tests.
>
> **Recommendation 1.3:** AHRQ, NIH, and federal health care providers should identify opportunities for and encourage pilot projects to demonstrate the use of EHRs for supporting clinical research and integrating pharmacogenomic data into clinical research databases utilizing existing standards and terminology.
>
> **Recommendation 1.4:** A multi-stakeholder workgroup, including clinicians, health IT specialists, industry, laboratories developing or performing pharmacogenomic tests, medical device/product reviewers, pharmacists, and researchers, should be formed to develop a core minimum data set (potentially including gene names, gene mutations, coded interpretations, and associated medications) and common data definitions available for inclusion of pharmacogenomics data with demonstrated clinical validity and utility in an EHR.
>
> **Recommendation 1.5:** The unidirectional information-flow from EHRs to clinical research applications (such as case report forms) should be prioritized for Use Case Development.

II. Clinical Decision Support in Health Care Delivery

The use of CDS capabilities within EHRs and related electronic clinical systems holds great potential to improve health care outcomes in the U.S. CDS provides clinicians, staff, patients, and other individuals with knowledge and person-specific information, intelligently filtered at appropriate times, to enhance health and health care. CDS encompasses, but is not limited to: computerized alerts and reminders to care providers; methods to bring care into compliance with clinical guidelines; generation of order sets, patient data reports and summaries, and

documentation templates; advice to promote more accurate and timely diagnoses; and tools that enhance clinical workflow.[13]

Over the past several months, numerous AHIC Workgroups have identified these CDS capabilities as a timely and important area of focus. To address this need, a CDS Ad Hoc Planning Group, comprised of representatives from the Consumer Empowerment, Electronic Health Records, Personalized Health Care, Population Health and Clinical Care Connections, and Quality Workgroups, was created in May 2007 to form a common framework through which a coherent and complete set of priorities for CDS could be generated. Recommendations prepared by the CDS Ad Hoc Planning Group were accepted on April 22, 2008 by the AHIC.[14]

The recommendation letter mentions the formation of a multi-stakeholder federal CDS Collaboratory.[15] The CDS Collaboratory is co-sponsored by AHRQ, the HHS Personalized Healthcare Initiative, and the Office of the National Coordinator for Health Information Technology (ONC), and will coordinate CDS efforts internal to the government. In addition, Recommendation 2.2 from the CDS Ad Hoc Planning Group described a public-private CDS entity, working with its stakeholders, that should plan a CDS infrastructure to serve the nation in the long term, and identify actions that its constituents can take to further the adoption of CDS. Looking across existing efforts within the public and private sectors, the public-private CDS entity should identify approaches where coordination, collaboration, and collective action can advance effective use of CDS. Specific deliverables may include:

- Formulate education efforts and business cases that promote integration of CDS within EHR systems and create incentives for use of CDS to support improved patient care quality
- Develop a framework to optimize the delivery of CDS interventions so that advice is delivered at the right time, place, and in a manner that enables consumers and health care professionals to act upon it in a timely manner
- Establish a communication forum for CDS stakeholders to promote identification of common interests and execution of mutually beneficial activities that advance widespread and effective utilization of CDS.

Recommendation 3.3 from the CDS Ad Hoc Planning Group described the development of a minimum data set of personal attributes that contribute to individualized care. Once the minimum data set has been created, the Healthcare Information Technology Standards Panel (HITSP) should develop interoperability standards for the personal attribute minimum data set. Interoperability standards should span EHRs and PHRs and should be added to the criteria for relevant certifications.

---

[13] Osheroff, J. A. et al. "A Roadmap for National Action on Clinical Decision Support." *J Am Informatics Assoc*, **2007**, *14*, 141-145.

[14] http://www.hhs.gov/healthit/documents/m20080422/6.2_cds_recs.html

[15] "To coordinate efforts internal to the government, a multi-stakeholder federal CDS Collaboratory, co-sponsored by Agency for Healthcare Research and Quality (AHRQ), the HHS Personalized Healthcare Initiative, and ONC, has been formed. This group will build upon a scan of CDS-related federal agency activities conducted in 2007, and will work to leverage the efforts and knowledge of multiple agencies to expedite development and widespread adoption of effective CDS capabilities." http://www.hhs.gov/healthit/documents/m20080422/6.2_cds_recs.html

Using the framework of the above CDS recommendations, the PHC Workgroup makes the following recommendations for pharmacogenomics:

> **Recommendation 2.0:** When the public-private CDS entity is developing strategies to incorporate accepted CDS technologies into health care information technology and clinical processes, and describing high level, standard workflows and types of CDS interventions that are applicable to health professionals' workflows, the electronic exchange of clinically useful pharmacogenomic and other relevant health information among the patient, pharmacist, and prescribing clinician should be considered.
>
> **Recommendation 2.1:** When developing a minimum data set of personal attributes that contribute to individualized care, the public-private CDS entity should include pharmacogenomic test information and/or interpretations as part of that minimum data set.
>
> **Recommendation 2.2:** AHRQ and NIH should continue to work with appropriate agencies and organizations, including clinical laboratories, to evaluate how pharmacogenomics-related CDS tools affect clinicians' and patients' decision-making, and to ensure that developed tools will be utilized by end-users. Clinician expertise and complicating factors such as comorbidities and polypharmacy need to be examined in combination with the CDS tools.
>
> **Recommendation 2.3:** The public-private CDS entity and CDS Collaboratory should include standards for reporting, annotating, tracking, and updating versions of pharmacogenomic and related algorithms. Algorithms should be stored in a CDS repository and should be continually updated as new variants and/or pharmacogenomic data are developed.

III. Integrating Pharmacogenomics into Medication Prescribing Practices

E-prescribing is one of the most mature forms of health information technology with about 70 percent of the 57,000 community pharmacies having the capacity to receive e-prescriptions, though only about 2% of all prescriptions are submitted electronically.[16] The National Council for Prescription Drug Programs has played a significant role in standards development for e-prescribing. By augmenting the information that is provided to pharmacies, pharmacists could become more engaged as a point-of-care resource providing assurances for patient safety, minimizing adverse events and improving health outcomes. Providing pharmacists with clinical data attributes, such as allergy, pharmacokinetic data, and pharmacogenomic results or interpretations, could improve communication, verify proper dosing decisions, and augment consumer education. Including CDS in e-prescribing systems may improve the safety, quality, efficiency, and cost-effectiveness of care.[17] This will require the development of standard terminology, metrics, and guidelines to optimize the messaging both to and from the pharmacy, examination of the workflow (clinician/prescriber, clinical laboratory, patient, and pharmacy),

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[16] *National Progress Report on E-prescribing*: http://www.surescripts.com/pdf/National-Progress-Report-on-EPrescribing.pdf

[17] Teich, J. M. et al. "Clinical Decision Support in Electronic Prescribing: Recommendations and an Action Plan: Report of the Joint Clinical Decision Support Workgroup" *J Am Informatics Assoc*, **2005**, *12*, 365-376.

and identification of the policy and technical issues associated with transmittal of laboratory test results into an EHR.

> **Recommendation 3.0:** HHS should work with stakeholders, including professional associations representing clinicians, clinical laboratories, pharmacists, and others, to develop a white paper on the opportunities and challenges associated with dispensing pharmaceutical drugs based on pharmacogenomic test-derived interpretations in inpatient, ambulatory, and mail-order services. Issues to consider may include: incorporation into workflow, identification of the party responsible for utilizing the dosing algorithm (which incorporates pharmacogenomic data with other clinical data), identification of contraindications, and ensuring that testing precedes dispensing, where appropriate.

> **Recommendation 3.1:** The information-flows between the clinical laboratory, patient, pharmacist, and prescribing clinician, including pharmacogenomic-based dosing interpretation of clinically validated test/drug combinations, within e-prescribing technology should be prioritized for Use Case Development.

Many efforts in PHC focus on the future health system; however, pharmacogenomics provides current opportunities to improve patient outcomes. For example, recent progress in elucidating the genetic basis for variations in drug metabolism and response has motivated the FDA to modify prescription drug labels (for example, warfarin[18], carbamazepine-containing drugs,[19] and morphine[20]) to suggest the use of genetic testing prior to commencing treatment. Timely and complete dissemination of this information to clinicians may be challenging, but existing programs (DailyMed,[21] Structured Product Labeling,[22] MedWatch,[23] and other FDA programs, such as FDA Alerts, Health Professional Information Sheets, news releases, podcasts, and Continuing Medical Education Programs) provide access for updated safety information on drugs and other regulated medical products and could be bolstered through the use of CDS or other web-based tools. It is likely that similar prescription label changes will follow additional pharmacogenomics research. Pharmacogenomic tests analyze variations in genes that may affect drug targets or drug metabolism, thus enabling optimal drug selection or dosing to avoid adverse events and optimize efficacy. Some of these tests are already used in practice or in clinical studies for a diverse group of conditions such as schizophrenia,[24] Attention Deficit Hyperactivity Disorder,[25] cancer chemotherapy (irinotecan),[26-27] and asthma and chronic obstructive

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[18] http://www.fda.gov/bbs/topics/NEWS/2007/NEW01684.html
[19] http://www.fda.gov/cder/drug/InfoSheets/HCP/carbamazepineHCP.htm
[20] http://www.fda.gov/bbs/topics/NEWS/2007/NEW01685.html
[21] http://dailymed.nlm.nih.gov/dailymed/about.cfm
[22] http://www.fda.gov/oc/datacouncil/SPL.html
[23] http://www.fda.gov/medwatch/
[24] de Leon, J. et al. "The CYP2D6 Poor Metabolizer Phenotype May Be Associated With Risperidone Adverse Drug Reactions and Discontinuation" *J Clin Psychiatry,* **2005,** *66*, 15-27.
[25] Trzepacz, P. T. et al. "CYP2D6 metabolizer status and atomoxetine dosing in children and adolescents with ADHD," *European Neuropsychopharmacology*, **2008,** *18*, 79-86.
[26] Innocenti, F. et al. "Genetic Variants in the *UDP-glucuronosyltransferase 1A1* Gene Predict the Risk of Severe Neutropenia of Irinotecan," *J Clin Oncology*, **2004,** *22*, 1382-1388.
[27] O'Dwyer, P. O, et al. "Uridine Diphosphate Glucuronosyltransferase (UGT) 1A1 and Irinotecan: Practical Pharmacogenomics Arrives in Cancer Therapy" *J Clin Oncology,* **2006**, *24*, 4534-4538.

pulmonary disease (leukotriene antagonists and theophylline).[28] A white paper commissioned by ONC and HHS published in 2005 provided several guidelines to help federal government activities concerning CDS in e-prescribing and related domains.[17] Within the recommended features and elements needed for an e-prescribing system to provide effective, high-value CDS, the white paper suggested that test results should be integrated with EHRs, and that genomic data, as it becomes available and clinically relevant, should be included as a data element. In addition to label changes, the evidence to support the use of these tests is still being developed. Exploration of standardized electronic methods to communicate these changes in labeling and evidence may increase clinician knowledge and, therefore, improve patient outcomes.

> **Recommendation 3.2:** AHRQ, CDS Collaboratory, and FDA should convene a meeting with various stakeholders, including associations representing clinicians, patients, and pharmacists; clinical laboratories that develop and perform pharmacogenomic tests; commercial drug database industry; EHR vendors; e-prescribing vendors; and other organizations to determine how information from FDA label changes may be integrated into electronic prescribing or CDS tools for point-of-care decision-making.
>
> **Recommendation 3.3:** National Library of Medicine (NLM) should lead an effort to complete and vet an ongoing activity to integrate structured genetic information, including pharmacogenomic test results and interpretations, into an EHR/PHR. This effort should include necessary normalization and translation of clinical standards into those compatible with the research setting.

These recommendations are supported by information obtained through research and testimony to the Personalized Health Care Workgroup, which is contained in the supporting documents available at http://www.hhs.gov/healthit/.

Thank you for giving us the opportunity to submit these recommendations. We look forward to discussing these recommendations with you and the members of the American Health Information Community.

Sincerely yours,

/John Glaser/
John Glaser, PhD
Co-Chair, Personalized Health Care Workgroup

/Douglas E. Henley/
Douglas E. Henley, MD
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[28] Weiss, S. T. et al. "Overview of the Pharmacogenomics of Asthma Treatment" *Pharmacogenomics J*, **2006,** *6,* 311-326.

Department of Health & Human Services
Office of the National Coordinator for Health Information Technology

American Health Information Community

Defining Key Health Information Technology Terms

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June 3, 2008

Building Consensus

- Literature review
- Multi-stakeholder workgroups
- Public forums and public comment periods
- Lexicographer input
- Contextual relationships

Major Themes

- **Interoperability is a common thread running through all terms and definitions**
- **Health-related information includes all aspects of care and health**
- **Interoperability distinguishes EHR from EMR**
- **Control of information distinguishes EHR from PHR**
- **HIE is a process, HIO is an oversight organization, and a RHIO is a type of HIO**

Health Records Terms and Definitions

Electronic Medical Record	Electronic Health Record	Personal Health Record
An electronic record of health-related information on an individual that can be created, gathered, managed, and consulted by authorized clinicians and staff within one health care organization.	An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one health care organization.	An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be drawn from multiple sources while being managed, shared, and controlled by the individual.

Health Records Terms: Key Concepts

- **EMRs prevail today, focused on care and information within a single organization**
- **Interoperability standards incorporated in EHRs in 2008 start the migration to information shared among organizations**
- **PHRs under the control of the individual, not the provider, are interoperable with provider records, and other health related sources**
- **PHRs are the source for diverse and varied applications to meet customer needs**

Network Terms and Definitions

Health Information Exchange	Health Information Organization	Regional Health Information Organization
The electronic movement of health-related information among organizations according to nationally recognized standards.	An organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards.	A health information organization that brings together health care stakeholders within a defined geographic area and governs health information exchange among them for the purpose of improving health and care in that community.

Network Terms: Key Concepts

- **Allow for efficient exchange of reliable and secure health related information**
- **Can connect EHR to EHR, EHR to PHR, and support population based approaches to improving health and care**
- **Use nationally recognized standards for interoperability, incorporate privacy and security policies and procedures, are governed by oversight structures that also ensure accountability**

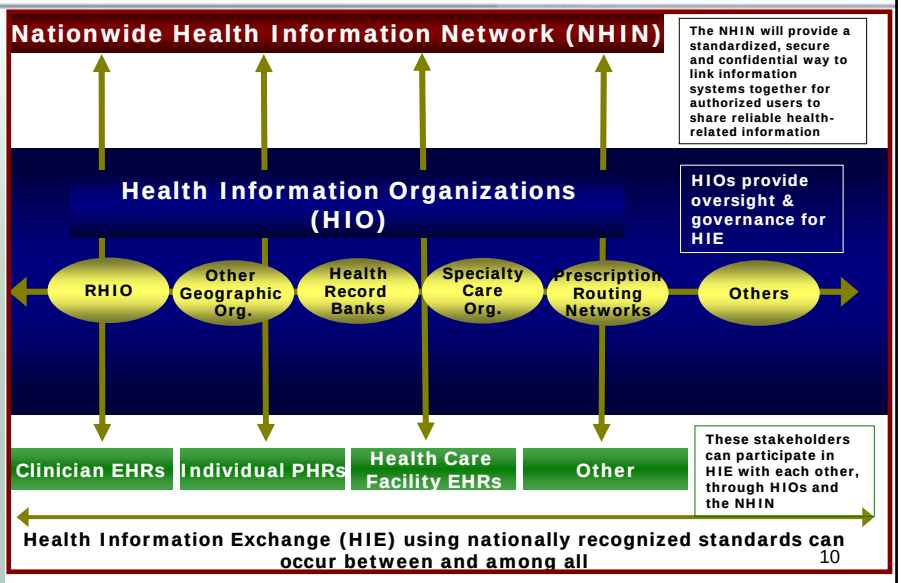
Network Terms: Key Concepts

- **HIE is a process, not a structure**
- **The HIE process incorporates nationally recognized standards and is not limited by geography**
- **An HIO provides oversight for various types of HIE processes: among specialty care entities, within a geographical area, health data banks, etc.**
- **HIO functions may include:**
  - maintenance of agreements
  - support for architecture
  - fiduciary responsibilities
  - conformance to nationally recognized standards

Network Terms: RHIO is a type of HIO

- **RHIOs are geographically bound**
  - Represents a contiguous geographic area
  - Scope can be local, statewide, or span state boundaries
- **RHIOs have distinct purposes and features**
  - Organized for purpose of improving health care in its community
  - Benefits and includes all stakeholders in defined area
  - Facilitates collaboration in transparent manner
  - Involves data-sharing between separate & distinct legal entities

Health IT Enabled Health and Care: The Future



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The National Alliance for Health Information Technology
Report to the Office of the National Coordinator for Health Information Technology
on

Defining Key Health Information Technology Terms

April 28, 2008

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FOREWORD

In 2004, United States President George Bush called for most Americans to have electronic health records by 2014. While few would have imagined what that really could mean to the providers of health care, patients and consumers, and those dependent on gathering health-related information from multiple sources, one thing was certain: he was not referring to electronic versions of the paper records used in most clinical settings at the time.

The types of electronic records that would support the outcomes that were and are still anticipated are part of a health information technology infrastructure that will ultimately allow authorized access to fully comprehensive patient and consumer health related information for multiple appropriate activities: patient care, consumer self-management of health, and a multitude of research, emergency response, and public health initiatives. Another part of that infrastructure is the system of health information exchange networks that can support secure and reliable information exchange within their constituency, and with other similar networks. Both the electronic records and the system of networks must, however, have incorporated recognized standards for interoperability and for the secure and reliable exchange of health information.

As of today, we do not have all the critical pieces in place to realize the vision. They are, however, just around the corner. The Certification Commission for Health Information Technology has incorporated basic interoperability standards for patient care as part of its 2008 certification criteria. Nine sites implementing the core specifications for health information exchange are the first of many that will constitute the Nationwide Health Information Network. We are on the cusp of a cataclysmic change in how health and care will be managed into the future as more and more information becomes available through expanded adoption of interoperable technologies.

Realizing the vision is not, however, just about the enabling technology. It's also, to quote Secretary Michael Leavitt in his keynote address at the February 2008 HIMSS Annual Conference & Exhibition in Orlando, very much about sociology and culture change. Both clinicians and consumers need to feel that privacy and security needs are addressed appropriately. Everyone must see the value in creating, exchanging, and using electronic health information, and contribute to its investment. And, as in any culture, we need to clearly communicate with one another, so that our health policies are well informed, products can be marketed with transparency, and protections can be applied to well-defined situations.

Culture change requires a consistent language that can support a system of public policies, private development, and outreach/educational initiatives that will allow the majority of Americans to experience the actual value of an electronic health information infrastructure.

Our next step, then, is to assure that this language is in place and represents a consensus on how terminology and definitions should be used as we move toward the 2014 goal. I am pleased that The National Alliance for Health Information Technology has convened this public dialogue and presents here the results.

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May 2008

EXECUTIVE SUMMARY

The potential for information technology to have an impact on health care safety, cost, and quality has never been greater. The technology to create, transmit, store and manage individuals' health data is rapidly advancing. Significantly, this potential is recognized at the highest levels of government and in the private sector as both confront the spiraling costs and inefficiencies of health care. As health IT initiatives gain momentum, there is increasing appreciation for the degree to which they can:

- Improve the coordination of care within the health care delivery system by increased sharing of health information among authorized clinicians, elevating the standard of care for everyone.
- Provide individuals with electronic access to their own health and wellness information, engaging them in opportunities for improving their health and well-being.
- Improve the health of the community using aggregated health data for research, public health, emergency preparedness and quality improvement efforts.

Realizing these benefits requires an underlying infrastructure that can support the use of patient-focused electronic health information, information that goes beyond the limitations of a specific provider, health plan or delivery system. It also includes the process of sharing health-related information in a secure manner, protecting the confidentiality of the information. The building blocks associated with this infrastructure are currently referred to as the electronic medical record (EMR) and/or electronic health record (EHR) for health care professionals, personal health record (PHR) for individuals, and health information exchange (HIE) to tie the infrastructure together. A regional health information organization (RHIO) organizes all of these components into a local infrastructure.

The recent surge of activity from both public and private sectors to use and share health-related information has proceeded without a discussion concerning what these building blocks actually are and how they fit together in a clearly understood model. Myriad meanings for each term emerged and the relationships among the terms were inadequately defined. There was, and is, no clear language underlying health IT adoption.

The ambiguity of meaning created by not having a shared understanding of what these key terms signify becomes an obstacle to progress in health IT adoption when questions about a term's definition and application complicate important policy expectations or directives, contractual matters, and product features. Differences in how a term is used can cause confusion and misunderstanding about what is being purchased, considered in proposed legislation, or included in current applicable policies and regulations.

To address these issues and to provide support for increased adoption of health IT, The Office of the National Coordinator for Health Information Technology (ONC) issued a contract to reach consensus on definitions for the terms EMR, EHR, PHR, HIE and RHIO. As discussions and public comments took place around the meanings of these terms it was noted that dual interpretations of HIE existed, as both a process and an entity. As such, there arose a need to clarify the difference between the process of information exchange and the oversight and accountability functions necessary to support that process. To address this need, a sixth term, health information organization (HIO), was added and defined.

In this report, The National Alliance for Health Information Technology (Alliance), under the guidance of BearingPoint, Inc., a management and technology consulting firm, summarizes the deliberations and conclusions of the two work groups that were formed to gain consensus on the definition of these terms. To assist the work groups in reaching consensus, a comprehensive literature review to identify existing definitions was performed, and public forums and public comment periods were conducted to vet the work while in development. This collaborative, consensus-building effort ran from September 2007 through April 2008. The two main objectives

of creating the proposed definitions were to eliminate confusion around the terms and to provide health care stakeholders with common understanding of the important components of the health IT infrastructure. The definitions in this report, when put into practice, will result in a number of benefits including:

- Health IT concepts expressed in a language that individuals comprehend.
- Standard terms for policy makers to use when drafting and evaluating policies.
- Important reference points for health IT initiatives.
- More effective contracting between health IT vendors and their customers.

These definitions will not, and are not intended to, solve all the challenges facing health IT adoption. However, they do represent an important foundation for addressing some important adoption issues.

Major themes from work group deliberations and public comments

Discussions arising from Alliance-led work group meetings and observations collected from two public forums and two public comment periods helped identify several major themes concerning electronic records and sharing of health-related information:

Interoperability is the common thread running through health IT terms. Interoperability is the essential factor in building the infrastructure to create, transmit, store and manage health-related information.

Nationally recognized standards are required to enable the flow of information. EHRs, PHRs, and HIE require the use of nationally recognized interoperability standards to enable the flow of information reliably, consistently, accurately, and securely.

The principal difference between an EMR and an EHR is the ability to exchange information interoperably. An EMR aligns with the prevailing state of electronic records today (whether the record is branded an EMR or an EHR). However, the movement of the industry is toward electronic records that are capable of using nationally recognized interoperability standards, which is a key defining component of an EHR. With the passage of time, electronic records not capable of exchanging information interoperably will lose their relevance. Thus the term EMR is on course for eventual retirement.

Control of information distinguishes EHR from PHR. The information in a PHR, whether contributed from an EHR or through other sources, is for the individual to manage and decide how it is accessed and used. Electronic portals of information on an individual that are hosted by a provider or payer organization, without transferring the control of the information to the individual, are not PHRs but rather examples of giving individuals access to information in an EHR.

Records contain health-related information. Because of their historical origin, the prevailing terms for electronic records retain an outdated differentiation based on a “medical” or “health” orientation. In fact, both types of records can and do contain a broad range of health-related information, and the differentiation is now along the lines of readiness to make that health-related information interoperable. In this report, health-related information refers to clinical and administrative, health and wellness data and information.

HIE is process. HIO is an oversight organization and RHIO is a type of HIO. In many instances, HIE has been used to describe both the process of health information exchange and the entity overseeing and governing the exchange. Consequently, HIE and RHIO were often used interchangeably. To provide greater clarity, three terms are defined to achieve both separation of meaning and a construct to accommodate a wide range of current and future organizations for information sharing.

Proposed Health IT Terms Definitions

The Alliance-led work groups recognize the definitions are written for three main constituencies: non-technical leaders in health care delivery, policymakers with responsibility and accountability for decisions in the area of health IT, and members of the general public who are being asked to participate more fully in their care and wellness activities but need education and tools to do so. It was also acknowledged that there are a number of parallel efforts to further specify these terms, particularly among standards development organizations. Although the work of these organizations was consulted, the definitions in this report are not intended to be detailed functionality specifications, but instead are intended to support and align with these efforts.

The proposed definitions are as follows.

Table 1: Records Terms

Electronic Medical Record	Electronic Health Record	Personal Health Record
An electronic record of health-related information on an individual that can be created, gathered, managed, and consulted by authorized clinicians and staff within one health care organization.	An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one health care organization.	An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be drawn from multiple sources while being managed, shared, and controlled by the individual.

Table 2: Network Terms

Health Information Exchange	Health Information Organization	Regional Health Information Organization
The electronic movement of health-related information among organizations according to nationally recognized standards.	An organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards.	A health information organization that brings together health care stakeholders within a defined geographic area and governs health information exchange among them for the purpose of improving health and care in that community.

Throughout the report, there has been an attempt to make the definitions clear, concise, and in keeping with good defining practice. However, the Alliance and the work groups recognize the importance of explaining some of the broader relationships and implications of each of the definitions. To this end, the report has been organized into the following sections:

- An introduction describing the nature of the problem and its implications, the benefits and potential uses of consensus definitions, the scope of the project, and the approach used to develop the definitions.
- A discussion of interoperability as the common thread running through health IT terms as a core foundational component.
- A records terms section presenting consensus definitions and rationale to explain the terms EMR, EHR and PHR.
- A network terms section presenting consensus definitions and rational to explain the terms HIE, HIO and RHIO.
- A look forward, envisioning how the definitions can support an interoperable infrastructure to realize the benefits of health IT.

PROJECT INTRODUCTION

A transformation in health care is being enabled by health IT, and the potential for information technology to have an impact on health care safety, cost, and quality is great. This potential is recognized at the highest levels of government and within the private sector as both confront the spiraling costs and inefficiencies of health care. As health IT initiatives gain momentum, there is increasing appreciation for the degree to which they can:

- Improve the coordination of care within the health care delivery system by increased sharing of health information among all authorized clinicians, elevating the standard of care for everyone.
- Provide individuals with electronic access to their own health and wellness information, engaging them in opportunities for improving their health and well-being.
- Improve the health of the community, using aggregated health data for research, public health, emergency preparedness, and quality improvement efforts.

The President of the United States signed Executive Order 13335 on April 27, 2004 to form the Office of the National Coordinator (ONC) for Health Information Technology with the objective of providing electronic health records to most Americans by 2014. Since that time, many efforts have been directed towards how best to equip health care to use and share health information electronically to improve the quality of care and to reduce costs.

As multiple groups grappled with how to achieve the President's vision, the following terms emerged to characterize some of the key building blocks of the envisioned health IT infrastructure: electronic medical records (EMRs) and/or electronic health records (EHRs) for health care professionals, personal health records (PHRs) for individuals and health care consumers, and electronic health information exchange (HIE) to enable efficient communication among these various records. A regional health information organization (RHIO) organizes these components into a local infrastructure.

Discussions around the meaning and dual interpretations of HIE as both a process and an entity brought into focus the need to further clarify differences between the process of information exchange and the oversight and accountability functions of information exchange. A new term, health information organization (HIO), was proposed to describe the oversight function of health information exchange.

While progress is being made toward establishing the envisioned infrastructure, health IT adoption remains relatively low.

- A recent survey conducted by George Washington University, the Harvard School of Public Health, Massachusetts General Hospital's Institute for Health Policy and RTI International, reported the EHR adoption rate for a minimally functional EHR among physicians in the ambulatory setting is only 14%. [1]
- Few PHRs exist and many Americans do not know what a PHR is and how it can be of value to them.
- Although standards harmonization and the development of interoperability specifications for use in health IT are being developed, inter-organizational health information exchange is not occurring on a widespread basis.
- Most RHIOs are in formative stages and working to identify viable business models.

These low rates suggest American healthcare culture has yet to embrace the importance and value of health IT. The ONC, recognizing the integral, vital need for clear, consistent language if health IT is to be woven into the fabric of our culture, issued a contract to reach consensus on

[1] Preliminary results were presented on January 22, 2008, to the American Health Information Community

definitions for five health IT terms: EMR, EHR, PHR, HIE, and RHIO. Under the guidance and management of BearingPoint, a management and technology consulting firm, The National Alliance for Health Information Technology (Alliance) conducted a literature review, convened workgroups, and held public forums and comment periods to clarify and create consensus and context around definitions for these terms.

The work contained in this report summarizes the deliberations and conclusions of two work groups, the Records Work Group, which developed definitions for the EMR, EHR and PHR, and the Network Work Group, which developed definitions for HIE, RHIO and, recognizing the need for a term to describe the oversight and governance functions of HIE, named and defined HIO.

The purpose of this report is to present the consensus definitions resulting from the project. To this end, the document has been organized into the following sections:

- An introduction describing the nature of the problem and its implications, the benefits and potential uses of consensus definitions, the scope of the project, and the approach used to develop definitions.
- A discussion of interoperability as the common thread running through health IT terms as a core foundational component.
- A records terms section presenting consensus definitions and rationale to explain the terms EMR, EHR and PHR.
- A network terms section presenting consensus definitions and rational to explain the terms HIE, HIO and RHIO.
- A look forward, envisioning how the definitions can support an interoperable infrastructure to realize the benefits of health IT.

Acknowledgement of work group members and an appendix of sources consulted during the course of this project are also included.

Identifying the Terminology Problem

Currently, the health IT terminology problem is not a lack of definition for the records and network terms, but rather, the existence of too many differing and even conflicting definitions. When conducting the literature review at the beginning of this project, the number of unique definitions found for each of the five terms ranged from 18 to 63. While there were common elements among some of the definitions, there were also areas of significant divergence. This lack of consistency is reflected in the current health IT landscape. For example, if different stakeholders were asked to define the term PHR, they would each likely come up with a different definition. A physician might define a PHR as a patient's view into components of an existing EHR or EMR, a patient might define a PHR as a stack of papers in the file cabinet at home, and a PHR vendor might define a PHR as a collection of electronic documents detailing the patient's health history. These different perspectives, and the lack of a consensus definition, make it difficult to have discussions on developing policies for, and technical standards around, PHRs.

Similar problems exist with the network terms. Some view the term HIE as the process of exchanging health information electronically, while others view the term HIE as the technical organization operating the network. Still others view the term HIE as an organization that governs the electronic exchange of health information. If the term HIE is defined as an organization, then it would need to be distinguished from RHIO. The term RHIO is limited to a specific regional or geographic component but is also used to describe community-based governance efforts.

The widespread adoption and use of health IT will require a cultural change whereby members of the general public recognize the value of health IT and come to expect access to electronic health information for both their providers and themselves. This culture change is dependent on a common understanding of what constitutes health IT and how electronic health information is created, stored, accessed, and used. Eliminating the confusion around the definitions for these terms will result in a number of benefits including:

- Health IT concepts expressed in a language that individuals comprehend.
- Standard terms for policy makers to use when drafting and evaluating policies.
- Important reference points for health IT initiatives.
- More effective contracting between health IT vendors and their customers.

These definitions will not, and are not intended to, solve all the challenges facing health IT adoption. However, they do represent a valuable foundational piece for beginning to address some important adoption issues.

PROJECT SCOPE

The scope of this project was to gain consensus on definitions for three records terms -- EMR, EHR, and PHR -- and two network terms -- HIE and RHIO. Definitions for these terms were developed in a health IT context; as such, the scope of the records terms has been limited to electronic records. The project acknowledges that many medical and health records exist in paper form, but incorporating the concept of paper records into these definitions was treated as out of scope.

During the course of evaluating the network terms, it became clear there was confusion over the dual use of the term HIE as both the process of electronic health information exchange and the organization supporting electronic health information exchange. As such, the report recommends that health information exchange (HIE) refer only to the process of electronic health information exchange. There is a recognition that HIE requires oversight to facilitate and govern the exchange of health-related information among organizations according to agreed upon standards, protocols and other criteria. A new term, Health Information Organization (HIO), was identified and defined to address this need. An HIO can take different forms, from a geographically based multi-stakeholder governance organization (a RHIO) to a contract/ business agreement or other structure that codifies decision-making authority.

In understanding the scope of this project, it is also important to consider the basic components of a good definition. The project team utilized a professional lexicographer for this purpose. Throughout the report, there has been a consistent attempt to make the definitions clear, concise, and in keeping with good defining practice: that is to say, the definitions must answer the question “what is it?” in a clear, simple and straightforward way. To this end, the following guiding principles were followed:

- Build upon existing definitions whenever possible.
- Increase the clarity and uniform understanding of key health IT terms.
- Be policy-neutral.
- Provide authoritative guidance.
- Develop definitions that are self-contained without reference to external sources.
- Incorporate flexibility into the definitions to accommodate future changes.
- Clearly indicate where we are describing what a term is today versus what it may become tomorrow.

It is important to understand what the definitions are not intended to do. While the definitions provide common language for working on important health IT issues that may lead to broader adoption, higher quality, or more efficient health care delivery, the definitions themselves will not produce these results. They describe several health IT foundation components as they are now, and as they may evolve in the future. The supporting text introducing the definition for each term and the discussions following the definition for each term address some of these broader relationships and implications.

These definitions were developed from a policy neutral perspective. The records and network terms may provide a foundation piece for policy discussions, but they are not intended to promote a particular agenda. There are many challenging policy issues related to these terms such as:

- Confidentiality, privacy, and security of patient data.
- Rights of access, permissions, and appropriate uses of patient data.
- Health information organizations and health information exchange funding and reimbursement models.
- Health Information Organization business and sustainability models.

The issue of what constitutes a provider's legal record was raised in the work group meetings. A legal record is understood to meet specific business needs for care, reimbursement, and disclosure; follow regulation and rules promulgated by Federal, State, or accrediting entities; and contain information as defined by the provider organization. As the health care system moves to adopt electronic records, what serves as a legal record becomes more complex. The data in a provider's electronic record on an individual patient is created and stored in different settings and in different formats, depending on the nature of the data. How these and other issues related to the legal nature of the electronic health information in EHRs and EMRs are currently being discussed in other settings and are therefore not addressed in this report.

It is important to understand for the purposes of this report the difference between an electronic record system and the underlying record itself. The underlying record consists of the health-related information on individuals that is available to be used for informing and improving health care and wellness activities. The record system supplies and performs the functions enabling information in the record to be used for various purposes. The scope of definitions in this report is limited to the underlying record, its content and characteristics. These definitions are not intended to be detailed functionality specifications for electronic record systems. Standards development organizations serving the health care field are conducting work in this area.

In all the records definitions – EMR, EHR and PHR - the content is described as health-related information, and in all the network definitions – HIE, HIO and RHIO – the content of exchange is described as health-related information as well. Health-related information encompasses health, wellness, administrative data, and information derived from public health and scientific research. It includes past and present observations and facts documented in the provision of health care that may be related to preventing illness and promoting wellness or that may be used in the process of informing consent.

Finally, in developing consensus definitions for broad use, it is important to avoid being too prescriptive. The definitions in this report have been intentionally developed at a broad level for general use over time.

ESTABLISHING AN APPROACH

The approach to developing consensus definitions is modeled after the approach used by the Alliance in 2005 to develop a consensus definition for the term "interoperability"[2]. This definition is cited in current federal Stark and Anti-kickback regulations. The approach involves conducting research, framing the issues, and reaching out to a broad spectrum of health IT stakeholders to reach consensus on definitions. Arriving at consensus on the records and network terms involved the following process:

- Conducting a literature review.
- Forming work groups to further the understanding of each term, gain consensus on definitions and evaluate public comments.
- Holding public forums and public comment periods.

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[2] In health care, interoperability is the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively and consistently, and to use the information that has been changed. The National Alliance for Health Information Technology, July 2005, *What is Interoperability?*

Literature Review

Prior to assembling work groups, the Alliance conducted a literature review to identify definitions already created and in use for the records and network terms. These definitions, drawn from leading organizations across sectors of the health care community, were collected, compared and contrasted. As a result of this research, a number of unique definitions were identified for each term as summarized in the table below.

Table 3: Unique Definitions

Health IT Term	Number of Organizations Identified as Having Meaningful Information about the Term	Number of Unique Definitions Identified for the Term
Electronic Health Record	99	63
Electronic Medical Record	35	26
Personal Health Record	52	36
Health Information Exchange	25	20
Regional Health Information Organization	21	18

The research results were compiled into a discussion document, establishing a factual basis for initial work group deliberations. The discussion document identified the following for each term:

- The most common definition in use today.
- Among definitions reviewed, the most common elements and most substantive differences.
- A discussion of terms and preliminary issues for the work groups to address.

Appendix A lists the organizations and sources researched for that compilation.

Work Groups

While the literature and analysis of similarities and differences among existing definitions were being compiled, two work groups were chartered to develop a more thorough understanding of each term and to champion consensus on the definitions: a Records Work Group for the records terms and a Network Work Group for the network terms. The work group formation process consisted of a public solicitation for nominations. Work group members were selected based on previous experience, expertise and availability to participate in meetings. A conscious effort was made to select work group members representing a broad cross section of health care stakeholders (e.g., payers, providers, consumer advocacy representatives, the government sector, employers, vendors, non-profits). A complete list of Records Work Group and Network Work Group members can be found in the Acknowledgements Section.

The work groups held their first meetings November 30, 2007. Work group members used the literature review discussion document as a starting point for their work and held a series of biweekly meetings to assess the terms, their definitions, their relationships, and their implications. Each work group member contributed expertise and shared work-in-progress with peers and colleagues in order to bring those additional comments to the work group. The deliberation process was designed to determine three basic characteristics of each term:

- What it is.
- What it is not.
- How it differs from the other terms.

Early in the work group deliberations, it was agreed that the definitions were intended for three main constituencies: non-technical leaders in health care delivery, policymakers with responsibility and accountability for decisions in the area of health IT, and members of the general

public who are being asked to participate more fully in their care and wellness activities but need education and tools to do so.

Public Forums and Public Comment Periods

The intent of the public forums and public comment periods was to give the broader public and interested stakeholders an opportunity to respond to the definitions as they were being developed. Public forums consisted of in-person meetings, whereby the definitions were reviewed and discussed.

Table 4: Public Forums Summary

Location	Date	Terms Discussed	Number of Attendees
Washington, DC	01/16/08	EMR, EHR, HIE, and RHIO	52
Orlando, Florida	02/26/08	EMR, EHR, PHR	25
Orlando, Florida	02/27/08	HIE and RHIO	32

Press releases, listserv announcements and outreach notices to stakeholder groups were broadcast to announce each public comment period. Draft reports were made available for download on the project website (www.definitions.nahit.org) and responses were submitted electronically to the website as well. During the first public comment period, 28 comments were received. During the second public comment period, 75 comments were received. The respective work group reviewed each comment, and the disposition of these comments is reflected in this report.

The definitions presented in the following sections of the report are the cumulative result of the literature review, work group deliberations, public forum and public comment periods, and the lexicographer review. The presentation for each term consists of three parts:

- An overview setting each term in a broader health care context, positioning it in relation to the other terms.
- A concise definition that communicates the essence of the term and differentiates it from the other terms.
- A narrative that lays out the core conceptual (not technical) attributes of each term and describes its meaning to create a more complete understanding of the definition.

THE CENTRAL ROLE OF INTEROPERABILITY

A common thread running through the health IT terms is the essential need for interoperability of health-related information. A goal pursued through the work of ONC is for electronic records to support the nation's transition from a provider-focused to a patient-focused system of health and care, the result being the ability to tap into many sources where information on an individual is kept under stewardship. Current ability to access multiple sources of information is restricted by at least two shortcomings: low rates of health IT adoption within the delivery system leading to limited opportunity to create and share health-related information electronically, and relatively few recognized standards for exchanging information reliably and securely, regardless of where the information originates or is being sent or received.

However, the health care field is beginning to facilitate agreement on, and induce adoption of, standards to enable interoperable exchange of information. The following definitions for electronic records and health information exchange acknowledge this process of facilitating interoperability by requiring the use of these standards as availability increases. Specifically, the definitions require the ability to use "nationally recognized interoperability standards," referring to a recognition process established by the Secretary of Health and Human Services (HHS). A principal source of standards for the Secretary to officially recognize is the American National Standards Institute's (ANSI) Healthcare Information Technology Standards Panel (HITSP), the federally supported body set up to harmonize interoperability standards. These standards are developed by a number of national and international standard organizations.

Until HHS recognizes a body of standards approaching the critical mass that enables a working level of interoperability, any definition that includes interoperability as a characteristic describes something that is currently very limited in its capacity to exchange health information. However, in order to arrive at the level of sophistication required of EHRs, interoperability must be a pivotal characteristic. And in order for EHRs to draw information from many sources through health information exchange, those networks of exchange must also be capable of using interoperability standards. Thus, electronic records and information exchange processes must be ready to use the increasing number of recognized standards as they become available.

A factor in the staged adoption of interoperability standards is the certification process for health IT products established by the Certification Commission for Healthcare Information Technology (CCHIT). In addition to developing minimum criteria for functionality, security and privacy features of EHRs, the CCHIT certification process requires health IT products to demonstrate they have incorporated the nationally recognized interoperability standards.

The combination of standards development efforts, formal recognition of nationally recognized interoperability standards, and phased implementation of standards into health IT products provides the basic foundation for electronic records and health information exchange to bring about a patient-focused system of health and care. The definitions presented here rely on this foundation.

HEALTH INFORMATION TECHNOLOGY TERMS

Health Record Terms Introduction

Electronic records have progressed during the past few decades as a useful alternative to paper-based records. Many types of health care organizations, from physician offices and hospitals to behavioral health and long-term care facilities, among many others, have and continue to realize benefits from creating digital versions of patients' paper charts. Sharing the patients' information across the organization and analyzing and interpreting information on a single patient or groups of patients is immensely valuable.

In transition. Current electronic record usage is primarily centered on the needs of authorized clinicians and staff for information regarding the patients treated within their organization. However, individuals seeking health care services typically go to many care providers who are not affiliated with one another. Each provider organization creates a separate record for the patient's care experiences. Without the ability to view multiple records on an individual from the multiple places where records are created, clinicians have an incomplete view of the available information that could well influence diagnosis, prevention and treatment.

The solution being pursued in health care is to enable the aggregation of health-related information into one record focused around a person's comprehensive health history rather than around one provider's limited view of that history, and to authorize access to that record wherever and whenever a person receives care. To accomplish this higher level of information aggregation and sharing, all the contributing organizations must be able to send and receive information using standards that facilitate the interoperable exchange of health-related information. Electronic records capable of employing such standards for interoperability, therefore, are pivotal to achieving patient-focused organization of health-related information. Electronic records that do not have this capability will be limited in their ability to keep pace with the future direction of health care.

The difference is interoperability. This distinction between records according to their ability to exchange information interoperably is the principal difference between an EHR, which can exchange information interoperably, and an EMR, which cannot. The EMR as defined in this report aligns with the prevailing state of electronic records today (whether they are branded as an EMR or an EHR). However, the movement of the industry is toward electronic records that conform to recognized standards for interoperability, which are defined as EHRs in this report. With the passage of time, electronic records that are not capable of exchanging information interoperably will lose their relevance. Thus, the term EMR is on a course toward eventual retirement, leaving EHR as the sole term referring to records of health-related information in electronic form that can be exchanged by health care organizations.

Engaging the individual. Paralleling the movement to patient-focused EHRs is the growing momentum to encourage individuals to be active participants in their health and care by giving them the means to establish and manage their own electronic store of health-care and wellness information. This personal health record, or PHR, is defined in this report in terms of an emerging state, the objective of which is to encourage individuals to pursue healthful lifestyles, manage health risks and chronic illnesses, access health and wellness services, and make more informed decisions.

In summary, EMRs and EHRs are tools for providers while PHRs are the means to engage individuals in their health and well-being.

Table 5: Electronic Health Records Definitions

Electronic Medical Record	Electronic Health Record	Personal Health Record
An electronic record of health-related information on an individual that can be created, gathered, managed, and consulted by authorized clinicians and staff within one health care organization.	An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one health care organization.	An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be drawn from multiple sources while being managed, shared, and controlled by the individual.

What is an electronic medical record?

Overview

In every individual health care encounter, clinicians have the need and responsibility to collect, retrieve and analyze data in the course of his or her attention to a patient. With the advent of computer-enhanced health care technologies, the EMR has come to represent the digital version of a patient's paper chart within a clinical setting, whether in physician offices or in hospitals or other care facilities where these activities are documented. It is expected that the information contained in an EMR be maintained in a secure manner that protects the confidentiality of the individual's information.

In addition to creating, storing and sharing information from within the health care organization it serves, an EMR can transmit and receive health-related information to and from external sources. But, it does not have the inherent capacity to use nationally recognized interoperability standards to send and receive, which distinguishes it from an EHR. Many options exist to send and receive by proprietary means: a lab issuing test results to a provider's designated computer, for example, or a data interface enabling a hospital to report a disease outbreak to a health department. Information also can be entered manually or scanned in from faxes, phone messages or paper-based reports. Various functionalities may permit an EMR to aggregate data points that have been entered, but they do not take advantage of standards-based interoperable data.

Because of this lack of interoperability, an EMR is limited to one health care organization. This does not mean a single physical location; under some circumstances, information can be shared among multiple facilities and still be within one EMR. For example, an electronic record used in a physician practice with several offices (intra-organizational) is still an EMR when all sites are using the same proprietary data structure and architecture and the information is not moving outside the confines of the organization using nationally recognized interoperability standards.

The scope of this definition is limited to the content and characteristics of the underlying record, not on the systems that perform functions enabling data in the record to be used for various purposes. Thus it is different from, and cannot be equated with, establishing detailed functional standards or criteria.

Electronic Medical Record (EMR)

An electronic record of health-related information on an individual that can be created, gathered, managed, and consulted by authorized clinicians and staff within one health care organization.

Understanding an EMR

The EMR's structure as a store of electronic information capable of being searched, categorized and analyzed makes it superior to the traditional paper chart for informing the care process. Nevertheless, proceeding from its historical basis as the digital version of a patient's chart, the EMR is a provider-focused view of the patient's health history. It comprises health-related information that is created by clinicians or that results from clinician orders and activity on behalf of a patient, such as diagnostic tests or prescriptions for medications. A main objective of an EMR is to improve the ability of a clinician to document observations and findings and to provide more informed treatment of persons in his or her care.

An EMR also can provide the underlying patient information for computerized functions such as drug-to-drug interactions, recommended care practices or interpretation of data to support and improve clinical decisions. However, these functions are limited by the extent of the information available in a provider-focused electronic medical record within a single health care organization.

What is an electronic health record?

Overview

The electronic health record (EHR) is the focus of efforts throughout the health industry to employ the most comprehensive information available to best inform the care delivery process. The definition recognizes that health-related information about a patient is available in multiple locations and systems and that, if presented through a common and user-friendly interface, this information can improve the ability of clinical personnel to support the best possible diagnosis, treatment, and health management decisions for and with an individual.

The ability to aggregate comprehensive information, whether physically within one record or virtually from records in multiple locations, is currently limited. Technical standards and common vocabularies for medical terms have yet to be agreed upon let alone implemented for many different types of data originating from many diverse sources. The potential for digitizing information and thus making it available to all involved in health care will improve over time, in step with progress in the interoperability of information and the increased adoption of EHRs within the delivery system.

In the past, a person's medical history was recorded primarily to document how clinicians in a single care organization treated that person's health needs during a clinical encounter. EHRs will help health care providers move to a more efficient way of organizing and sharing information beyond the scope of one organization or single encounter. EHRs take advantage of advances in computer performance and electronic communication to present a patient-focused view of an individual's health information recorded by various provider facilities—such as physician offices, hospitals, long-term care facilities, behavioral health centers, home-based care, laboratories and pharmacies—and authorized clinicians, such as physicians, nurses, social workers and others involved in an individual's care.

EHRs will allow the recorded narratives, newly added observations and test results for a patient to be brought together from multiple settings and locations of care providers into one health record. In addition, information from administrative sources may also be included, such as: claims data from health plans; formulary and medication data from pharmacy benefit managers, and demographic data. It is expected that the information contained in an EHR be maintained in a secure manner that protects the confidentiality of the individual's information.

The scope of this definition is limited to the content and characteristics of the underlying record, not on the systems that perform functions enabling data in the record to be used for various purposes. Thus it is different from, and cannot be equated with, establishing detailed functional standards or criteria.

Electronic Health Record (EHR)

An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one health care organization.

Understanding an EHR

An EHR is patient-focused in that it is not limited by what a single provider organization is able to accumulate on behalf of a patient under its care. Through the capabilities of interoperability, an EHR becomes an authorized means to access information from whatever sources have chronicled the health care experience of a patient over time. The boundaries of an EHR are built not around the organization documenting the information but around the patient and his or her health-related information. Though it is patient-focused, it is managed and used primarily by

authorized care providers, as well as by members of their staff who have a need to access the EHR to support the process of care.

Cradle to grave. As the information in an EHR is drawn from multiple organizations, the envisioned goal is for it to be a comprehensive, longitudinal record of an individual's pertinent health history. Due to the depth and breadth of data, an EHR thus offers a perspective on changes in health and medical conditions over time.

Information richness. Examples of information that can be contributed to and accessed in an interoperable EHR include:

- Past and current clinical information incorporated from all organizations that have been engaged in an individual's care or health maintenance.
- Administrative information pertinent to making clinical judgments and cost-sensitive decisions. One example is the multiple formularies used to select medications based on a patient's insurance benefits.
- Population-based data from sources such as disease registries and initiatives to detect disease outbreaks.
- Information that can be interjected into a clinical situation or used to interpret data on an individual to support and improve clinical decisions. Examples include alerts about harmful interactions of one drug with another, and formulas for medication dosing based on patient-specific conditions such as diabetes and factors such as age and weight.
- Information on evidence-based medicine, scientific research studies, or environmental situations.
- Information from remote monitoring devices, which capture real-time data on vital signs, cardiac or respiratory status, lab test values, etc.
- Information provided by PHRs, including patient-entered documentation, to supplement and enhance knowledge of a person's health status and initiative.

EHR or PHR? Through various technological means, selected content in an EHR can be made available for individuals to view and use in guiding activities of health and wellness through what is called a "patient portal." The health care provider operating the EHR system typically controls the portal. Many of these portals are given the name PHR, but the source of control of the information is important in determining whether this model is a PHR or remains within the scope of an EHR. To be a PHR, access to the record must be managed and controlled by the individual. Information that passes from an EHR to a PHR transfers to the control of the individual.

What is a personal health record?

Overview

The growing importance of the participation of individuals in their own care and wellness activities is the impetus behind the vision for personal health records. By enabling and encouraging individuals to become more engaged in their health and care, and by providing the means to document, track and evaluate their health conditions, a PHR can lead to more informed health care decisions, improved personal health status, and ultimately, reduced cost and improved quality of health care.

The current and largely rudimentary manifestations of what some call PHRs in electronic form begin to address personal health management objectives by providing some information on health care services and allowing individuals to enter information. Yet, PHRs have the potential to be a robust, better-assembled and more organized source of both clinical and wellness information for an improved level of clinical, health and wellness decisions. The anticipated result is a well-rounded, complete picture of an individual's health that extends beyond the care provided by the delivery system. Given the longitudinal nature of a PHR, the time period for this information could conceivably be as long as "cradle to grave."

Though a portion of the information in a PHR may originate from health care providers, health insurers or third party administrators, the control of information transfers to the individual when it becomes part of the PHR. By contrast, current internet-based portals of information on an individual that are hosted and maintained by a provider or payer organization, without transferring access and control and use of the information to the individual, are not considered PHRs based on this definition.

Personal Health Record (PHR)

An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be drawn from multiple sources while being managed, shared, and controlled by the individual.

Understanding a PHR

The most salient feature of the PHR, and the one that distinguishes it from the EMR and EHR, is that the information it contains is under the control of the individual. The concise definition above names the individual as the source of control, but that leaves room for others acting in the individual's interest—their agent or agents—to have control over access to the PHR. An agent may be expressly designated by the individual but not in all cases; examples of an agent acting for an individual include parents acting for children, or, in the later stages of life, children acting for parents.

Exercising control. The individual is distinctively the guardian of information stored or accessible within a PHR. Similar to the role of a librarian, a person managing a PHR decides what volumes of information to include, how they are maintained and ordered, and who can read them or "check them out." Standards and policy will need to determine if and how individuals can delete or modify information in a PHR that originated from an EHR and how these modifications are communicated to other providers with whom the data in the PHR are shared.

Portability. Having control also means that an individual's PHR can exist independently of the entity that sponsors it—the PHR is portable. This requirement for portability excludes models in which sponsors such as health insurers or health care providers give individuals access to health-related information that is dependent on the individual remaining with that sponsor.

Inputs into the store of information.

To reiterate, the long-term goal of a PHR is to be a lifelong resource of pertinent health information for an individual. Thus it should have both the depth and breadth of information to enable individuals to become more engaged in their own healthcare as they move from being passive recipients to active participants in their personal health management. The health information in a PHR can be drawn from a broad range of possible sources. Significant sources may include, but are not limited to:

- Health care providers–Including hospitals, skilled nursing homes, long term care, and other facilities; pharmacies, lab, and diagnostic facilities reporting test results.
- Health care clinicians–Including physicians, nurses, behavioral health professionals, registered dieticians, chiropractors, and other licensed or certified care providers.
- Medical devices–Instruments, machines and implanted devices monitoring clinical indices, for immediate use as well as for historical purposes.
- Wellness promoters–Entities supplying services or information to generate and maintain good health, such as fitness centers, rehabilitation experts, and complementary/ alternative medicine practitioners.
- Individuals–Self-generated information for personal management or information for care providers, including information about allergies, prescribed medications, eating habits, exercise objectives, the progression of an illness or recovery from it, and preferences regarding care in various circumstances.
- Health insurers–Information arising from claims for insurance payments, disease management programs recommending certain actions and collecting results, updated information on drugs in a formulary, and other coverage policies specific to an individual.
- Public health–Government health departments, disease surveillance and immunization programs, school-based care providers and social workers, and nongovernmental organizations engaged in health and wellness.
- Research institutions–Information about opportunities to engage in clinical trials and studies, and recently published results of interest to the individual.

The sum of these and other inputs is a well-rounded picture comprising clinical information, administrative information, and wellness information for individuals to employ and impart to others at their discretion.

Health Network Terms Introduction

Networks for exchanging health related information are essential to aggregating patient-focused information into EHRs and PHRs as well as to developing a population-based approach to improving care practices and preventing illness. These networks are beginning to take shape in localities and regions around the nation, and there is a need to enable these networks and their participants to exchange health-related information electronically on a widespread, interoperable basis with appropriate privacy, security, and confidentiality safeguards in place.

Nationally recognized interoperability standards are a necessary component of the definitions for the records terms. However, the network terms require interoperability plus an additional set of nationally recognized standards to enable the flow of information reliably, consistently, accurately and securely. This concept is reflected in the definitions.

The terms that facilitate understanding of the concepts closely associated with building health information exchange networks must address two principal components of a network endeavor:

- The process of sharing health-related information using nationally recognized standards.
- The need for an oversight structure to facilitate this sharing of health-related information and to be accountable for its performance.

The two terms under examination for their role in describing information networks—HIE and RHIO—address these two components, but further clarification is needed.

Eliminating Confusion. As an oversight structure, a RHIO describes a certain type of arrangement with distinct attributes relating to governance and geography. But it is not adaptable enough to suffice as a term that can encompass the wide range of organizational forms that an information-sharing structure can take, including forms yet to be envisioned. This shortcoming has led to the increasing usage of the term HIE to represent an oversight structure with the requisite flexibility. However, the term HIE at its core describes the process of sharing information. Continuing its dual meaning as the oversight structure as well as the process perpetuates confusion over the term, which runs counter to the objectives of clearly assigning meaning to each term and distinguishing one term from another in discussions about health information technology.

Proposed new term. Drawing from discussions in the Network Work Group and comments received in public forums and written public comments, two possibilities emerged and were considered; both of them are adaptations of existing health IT terms:

- Health information organization (HIO), identifiable as the root element of RHIO without the boundaries of geography assigned by the use of the modifying word *regional*.
- Health information exchange organization (HIEO), identifiable as the organizational entity that undertakes the oversight and governance of the HIE process.

Each alternative had significant support. In the final stage of consideration, consensus developed around HIO as more straightforward and distinguishable from HIE. HIO also lends itself to being the overarching term to describe an organization while having the built-in capacity to include a modifier for more specific identity: state-level, pediatric, behavioral, etc. It embraces RHIO as one kind of HIO while opening up the opportunity for other HIOs that are not geographically based.

Table 6: Network Terms

Health Information Exchange	Health Information Organization	Regional Health Information Organization
The electronic movement of health-related information among organizations according to nationally recognized standards.	An organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards.	A health information organization that brings together health care stakeholders within a defined geographic area and governs health information exchange among them for the purpose of improving health and care in that community.

What is health information exchange?

Overview

Health information exchange (HIE) refers to the process of reliable and interoperable electronic health-related information sharing conducted in a manner that protects the confidentiality, privacy, and security of the information. Essential to this process is the capability to employ nationally recognized standards as they are established incrementally, further enabling interoperability, security and confidentiality of the information as well as authorization of those who access the information.

Networks that are self-contained, such as those linking a hospital to affiliated practices, to other hospitals in an organization or to labs, can exist without having to employ nationally recognized standards. In the case of networks that make the exchange of information possible solely through proprietary means, the process is not considered HIE under the definition below. HIE at minimum must be technologically ready to conform to nationally recognized standards as they are available.

HIE supports the sharing of health-related information to facilitate coordinated care through the utilization of EHRs. HIE also provides key information to individuals to promote health and wellness through population of PHRs, and can be used to support research, public health, emergency response, and quality improvement. In addition, HIE enables the sharing of health-related information among health care organizations and with individuals on a local, regional, and national basis. This interplay of electronic records and health information exchange is an important component in establishing the basics of an infrastructure that will become the Nationwide Health Information Network (NHIN).

Health Information Exchange (HIE)

The electronic movement of health-related information among organizations according to nationally recognized standards.

Understanding HIE

To act as the medium of interoperable exchange between electronic records and organizations, HIE must itself meet nationally recognized interoperability standards. In addition, other classes of standards enabling the flow of information safely, consistently, accurately and securely must be part of the requirements for HIE. Interoperability, security and other standards required for HIE are in various stages of being developed and recognized by HHS. The definition of HIE includes readiness to use these developing information exchange standards; these standards for interoperability and information exchange, used consistently in HIE, will contribute to the foundation of what will become a Nationwide Health Information Network (NHIN).

HIE is not bound by geography–it can tie together sources of data from anywhere, whether within a small area or scattered throughout the nation. HIE can bring together a national network of labs, the network employed by entities representing disease communities, or an organization that facilitates the electronic prescribing of medications, etc.

What is a health information organization?

Overview

The process of HIE requires a formal degree of oversight to facilitate and govern the exchange of health-related information between organizations. The first incarnation of this oversight function to emerge from the marketplace was the *regional* health information organization or RHIO. But as different business and technological arrangements came into being to foster exchange of health-related information, they did not fit well into the confines of a RHIO as it was becoming defined by such characteristics as geography and community-based governance. To effectively account for and describe the range of possible organizational types, a term to uniquely define oversight organizations is necessary.

The term HIO affords an opportunity to be as general or specific as desired when referring to the arrangements governing the exchange of health information and identifying the nature of participation. As one result of this approach, the term RHIO can be placed in its proper perspective and defined distinctly. Thus a RHIO is positioned in this report as a type of HIO with a well-defined purpose and participation, one among many other potential types of HIOs with different purposes, participants and contractual agreements. Examples of other types of HIOs include health data banks, specialty care organizations, and integrated delivery networks (IDNs). Other types of HIO organizations can, if desired, differentiate themselves by substituting another defining word and acronymic letter ahead of the root term HIO.

Health Information Organization (HIO)

An organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards.

Understanding an HIO

The purpose of an HIO is to perform oversight and governance functions for HIE. Oversight functions of an HIO may include, but are not limited to:

- Facilitation of operations associated with the movement of information—assuring that hardware, software, protocols, standards, stakeholders and services supporting the interoperable exchange of health-related information are available and engaged.
- Fiduciary responsibility for the assets, accountability for abiding by regulatory requirements for handling personal health information, and adherence to standards enabling interoperable information exchange.
- Maintenance of information sharing agreements, business associate agreements, or other such contracts.
- Adoption and maintenance of standards ensuring interoperability while protecting the confidentiality and security of the information.
- Making decisions regarding certain types of information for which no nationally recognized interoperability standard is available.
- Developing and sharing best practices among organizations.

Although an HIO is identified as the organization overseeing HIE among disparate entities, HIE can also be implemented within a single organizational structure--for example, an integrated health care delivery system that converts from a proprietary, non-standard information exchange architecture to HIE architecture using nationally recognized standards. The health care system benefits by being in a position to exchange health-related information with other HIOs as they develop and mature.

What is a regional health information organization?

Overview

A RHIO is first and foremost a governance entity whose purpose is to facilitate the accessibility and exchange of health-related information on individuals within a contiguous geographic area for the benefit of the community in that area. A RHIO exists to supplement and enhance efforts to improve the quality, safety and efficiency of health and care on behalf of the individuals within its delineated geographic area. In essence, a RHIO is a type of HIO that is mission-driven and geographically bound.

Prominent entities in a RHIO include those that create and maintain health-related information and may include any organization, individual or interest group with a stake in improving health care through efforts to make health information more widely available, using appropriate security measures to protect the privacy of individuals as well as the confidentiality of their information. Groups of stakeholders may include:

- Health care institutions and personnel that render care.
- Businesses and government agencies that reimburse for those services.
- Researchers and professionals who are engaged in health improvement activities.
- Public health agencies.
- Consumers of health care.

HIE within a RHIO's geographic area is the chief means by which its objectives are achieved. The RHIO enables, facilitates and fosters collaboration among stakeholders to attain a useful level of information sharing through HIE. A RHIO may operate directly or contract for HIE services.

Regional Health Information Organization (RHIO)

A health information organization that brings together health care stakeholders within a defined geographic area and governs health information exchange among them for the purpose of improving health and care in that community.

Understanding a RHIO

To be designated a RHIO, an entity needs to have certain core features. These attributes distinguish it from other organizations that do not or cannot execute the distinct purpose and responsibilities of a RHIO.

An organization designated as a RHIO:

- Must involve data-sharing participants that are separate and distinct legal entities operating within a defined geographic area whose collaboration through the RHIO will cross organizational boundaries.
- Must intend to benefit the population in the community. This requires that stakeholders come from the defined geographic area and that the RHIO provides well-defined and transparent processes to facilitate the interoperable exchange of health information across the range of participating stakeholders.
- Must be inclusive and convene various types of stakeholders in the delineated geographic area who are vested in improving the health of the community.
- Can arrange for the provision of additional technical and operational services supporting its primary purpose. Such services may vary based on stakeholder needs and a range of environmental factors. Examples include:

- The technology and support for physicians to create and use electronic records, delivered to their places of work through Internet connections by application service providers (ASPs).
- Electronic exchange of messages in a secure format to report and distribute medical test results.
- Data on specific patients to first responders in a community; for example, whether a patient has signed a DNR (do not resuscitate) order.
- Coordinated electronic health record and personal health record platforms for the region.

The “regional” in RHIO defines a variable area that is less than national but can be broader than legislative boundaries (i.e. state lines, city limits, etc.) This latitude allows the determination of geographic boundaries logical to a set of stakeholders seeking to pursue the objectives of a RHIO. A RHIO can be organized to support a community, groups of communities, a statewide area or a region crossing state boundaries.

However, not all organizations with a geographic identity that are established to oversee and govern HIE must define themselves as RHIOs. For example, state-level HIOs that coordinate the consistency of information protocols, business rules and other components of RHIOs within the state do not have to meet the special requirements of a RHIO just because they are defined by the geography of a state. Their mission, objectives and manner of participation can be factors defining a different sort of HIO classification.

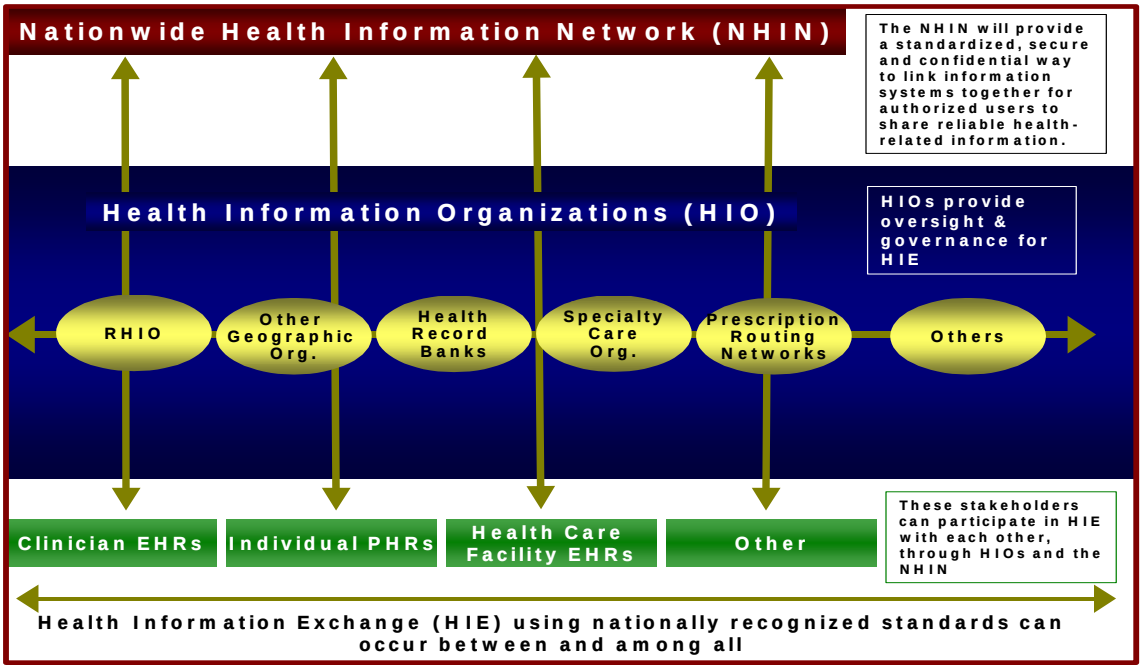
HEALTH IT ENABLED HEALTH AND CARE: THE FUTURE

Health care visionaries foresee a time when all types of health-related information exist electronically and can be reliably and securely accessed by any number of authorized parties and entities to improve the health of an individual, a specific community, or the U.S. population as a whole.

The integration of electronic records that can communicate with each other, governance and oversight organizations, and health information exchange processes will establish a larger and fully connected infrastructure to support all aspects of health and care.

The question then arises as to how current work supports this vision, and where this vision might take us. The following is a graphic representation of how the components of the proposed infrastructure integrate.

Diagram #1



While electronic records of health information are distinct entities now, it is clear that at some point in the future, data within them could meld, and various portals or views to the information would be developed to support the needs of providers, individuals, researchers, public health, and others engaged in health and wellness. This will bring additional benefits we can only imagine today, such as:

- **Personalized health care.** Rich information of this type would expand research capabilities to a level of patient specificity not currently possible. Diagnostic options and treatments could then be tailored to each individual's characteristics, genetic makeup, and preferences.
- **Knowledge management.** The ability assimilate and present the results of both empirical and traditional research in a far more timely fashion than is currently available would assure the accessibility of more evidence-based care appropriate to the circumstance.

- **Expectation of quality.** Dissemination and integration of the best knowledge available into systems that present the information in timely and useable formats would assure each individual that he or she is experiencing the highest quality of care we all will come to expect:

The vision starts today

The beginnings of this new era are not in the distant future. The Secretary of Health and Human Services has recognized a number of interoperability standards that will be included in the 2008 Certification Commission for Healthcare Information Technology certification process. Adoption of certified EHRs among clinicians and hospitals is expanding. Certification of interoperable PHRs is expected by 2009. Health information exchange standards have been formulated and are currently being implemented in nine trial sites of the Nationwide Health Information Network and within the Federal government. The process of adding nationally recognized interoperability standards is ongoing in HHS. These activities underscore the importance of defining and understanding the components of the emerging network for information sharing and how they will work together.

2008 is a pivotal year for health information technology. Adoption of the proposed common language will support more widespread adoption of the critical components necessary to transform our fragmented system to one that can support optimal health and care.

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APPENDIX A: REFERENCES - ORGANIZATIONS & LITERATURE REVIEWED

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Allscripts http://www.allscripts.com

Amazing Charts. http://www.amazingcharts.com/product/theproductframeset.htm

C
Cerner. http://www.cerner.com/public/Cerner_3.asp?id=27263

ChartLogic. http://www.chartlogic.com/

E
eClinicalWorks. http://www.eclinicalworks.com/code.php

H
Health Communication Systems.
http://www.healthcomsys.com/products/emrenterprise/default.asp

I
InteGreat. http://www.igreat.com/productdescriptions.cfm

ISALUS Healthcare. http://www.isalushealthcare.com/services/clinical/overview/chartshare/

M
Medicat. http://www.medicat.com/EMR.htm

Misys Healthcare Systems. http://www.misyshealthcare.com

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P
Practice Partner. http://www.practicepartner.com/pr/whyanemr.htm

S
SigmaCare. http://www.ehealthsolutions.com/display.asp?content=resource/terms

SOAPWare. http://www.docs.com/

V
VisualMed Solutions. http://www.visualmedsolutions.com/

Vendor Websites (PHR)

B
The Bartlett http://www.pehrtech.com/products.html

C
CapMed http://www.capmed.com

CareKey Personal Health Manager http://www.carekey.com/PandS/PHM.asp

Children's Medical Organizer http://www.childrensmn.org/cmo

D
Dossia http://www.dossia.org/consumers/faq#one

F
Follow Me http://www.followme.com/index.html

H
HandyMedical http://www.handymedical.com/

Health Records Online http://www.healthrecordsonline.com/

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HealthFrame Personal Health Record http://www.recordsforliving.com

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I

iHealth Record http://www.ihealthrecord.org/faq.html

Invidio Health http://www.indivohealth.org/pages/concept

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L

Laxor Personal Health Record http://www.laxor.com

M

MED http://www.medicalert.org/Main/technology02.aspx

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MyHealth 123 http://individual.myhealth123.com

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N

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O

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P

Personal Health Record System http://www.telemedical.com/records.html

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R

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